

GEORGIAN MEDICAL NEWS

ISSN 1512-0112

NO 7-8 (376-377) Июль-Август 2026

ТБИЛИСИ - NEW YORK



ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии
საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

Monthly Georgia-US joint scientific journal published both in electronic and paper formats of the Agency of Medical Information of the Georgian Association of Business Press.
Published since 1994. Distributed in NIS, EU and USA.

GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებშიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman (Кириллица)**, для текста на грузинском языке следует использовать **AcadNusx**. Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи.** Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - <http://www.spinesurgery.ru/files/publish.pdf> и http://www.nlm.nih.gov/bsd/uniform_requirements.html. В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректуре авторам не высылаются, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or computer-printed on a single side of standard typing paper, with the left margin of 3 centimeters width, and 1.5 spacing between the lines, typeface - **Times New Roman (Cyrillic)**, print size - 12 (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf

In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

**Articles that Fail to Meet the Aforementioned
Requirements are not Assigned to be Reviewed.**

ავტორთა საყურადღებო!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე, დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx**. შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემავჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრაფიის ფოტოსურათები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შედეგების ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფხიხლებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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COMPARATIVE EFFICACY OF 200 UNITS VERSUS 155 UNITS OF ONABOTULINUMTOXIN A FOR CHRONIC MIGRAINE

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Abstract.

Background: Migraine is a common neurological condition; it can be classed as episodic or chronic. In chronic migraine (CM), one of therapies have been revealed efficacy is onabotulinumtoxin A (OnaBT-A).

Aim of Study: To confirm that the effect of OnaBT-A treatment is dose dependent for the treatment of CM

Material and methods: This prospective, randomized, comparative study was carried out at a private neurological clinic in Mosul, Iraq. This study comprised a total of 106 patients who met the diagnostic criteria for CM. Two groups of patients were formed. The first group received 200 U of OnaBT-A by local injection, the second group received 155 U. Each group received OnaBT-A at the start of the trial, as well as after 12 weeks. The outcome indicators which include: monthly headache frequency, attack severity, duration of headaches, and disability, were collected and recorded at the baseline, at week 12 and at week 24.

Results: All headache outcome variables showed significant improvement with both treatment regimens. The efficacy of these treatment approaches is confirmed by the statistically significant p-values' consistency across both groups. The most significant gains were seen in the 1st group with the higher dose.

Conclusions: The study concludes that administering 200 U of OnaBT-A, significantly decreases the frequency and duration of headaches when compared to 155 U. It recommends considering this dosage for patients who do not accomplish adequate relief with 155 U of OnaBT-A. The promising outcomes suggest a need for further studies into long-term effects and evaluation of higher dosages.

Key words. Chronic migraine, onabotulinum toxin A, Dose dependent efficacy, preventive treatment.

Introduction.

Migraine is a chronic neurological condition characterized by throbbing, typically unilateral headaches that worsen with physical exertion and are accompanied by nausea, vomiting, photophobia, phonophobia, and, in many cases, cutaneous allodynia [1].

Migraine can be classed as episodic or chronic [2]. Chronic migraine (CM) represents a disabling disease that affects around 2% of the population. CM is characterized as a headache lasting ≥ 15 days per month for more than 3 months, with ≥ 8 days exhibiting migraine symptoms [3].

The purpose of preventative migraine treatment is to decrease the severity, frequency, duration, and functional disability of headache attacks, as well as enhance responsiveness to and minimize the usage of acute medicines [4]. Additional advantages of preventive therapy include the potential to lower health-care costs [5].

In CM, two therapies have revealed efficacy: topiramate and onabotulinum toxin A (OnaBT-A) [3].

Patients in clinical trials of preventative therapies for CM have historically been classed as treatment responders or nonresponders based on the binary criteria of having at least fifty percent reduction in the frequency of headache day [6].

The discovery of botulinum toxin (BT) therapeutic effect as a migraine prophylaxis was coincidental. Dr. Kerne hypothesised, during the War of Napoleon (1795–1813), that the paralytic effect of BT could be utilized therapeutically. Dr. Scott would be the first person who use BT therapeutically to cure strabismus in 1980. Since that time, it has been used to treat a variety of conditions, such as hyperhidrosis and muscular spasticity. Nonetheless, facial plastic surgeon Dr. Binder observed in the 1990s that several patients who received BT for cosmetic wrinkles experienced improvements in their migraine attacks [2,3].

The mechanism of paralytic action of BT is by binding to the terminals of skeletal cholinergic nerves.

BT prevents CM through a variety of intricate and poorly understood mechanisms. It suppresses peripheral sensitization and has a secondary inhibitory effect on the development and maintenance of central sensitization. It prevents the release of calcitonin gene related peptide (CGRP), substance P, and glutamate within the cranial sensory neurons [2,3].

“The European Medicines Agency” and “the Food and Drug Administration of the US” both approved OnaBT-A for the prophylaxis of CM in 2010. “The National Institute for Health and Care Excellence” recommended its usage in 2012. It has not been found that OnaBT-A is helpful for tension-type headaches or episodic migraines [3].

effectiveness of OnaBT-A in CM has been validated by multiple real-world trials and meta-analyses [2]. The PREEMPT-1 and PREEMPT-2 studies established class one evidence for OnaBT-A [3].

The use of OnaBT-A has significantly expanded since it was approved. The European Headache Federation has determined that a guideline for the use of OnaBT-A in CM is necessary and for this purpose an expert panel was appointed and tasked with creating the current guideline, which offers recommendations for the administration of OnaBT-A in CM [3].

Because there is significant number of the patients still have frequent attacks after using the standard therapeutic dose and there is no clear data about using higher doses, this study is accomplished.

Confirming that the effect of OnaBT-A treatment is dose dependent are the goal of the current study.

Materials and Methods.

This prospective comparison study as randomized trial was carried out at a private neurological clinic in Mosul, Iraq. The

patients who met the diagnostic criteria for chronic migraine in "the International Classification of Headache Disorders, 3rd edition (ICHD 3)" [7] were of both sexes, between the ages of 18 and 60. During the three-month baseline period, patients were required to provide data every day. Migraine days are defined as calendar days with four or more hours of continuous headache. Ethical approval for this study was obtained from the Research Ethics Committee at the Nineveh University/ College of Medicine.

Two groups of patients were formed. The first group received 200 U; the second group received 155 U.

Patients who met eligibility criteria had been randomly assigned in a 1:1 allocation ratio to either the 200 U or 155 U OnaBT-A therapy group after the baseline observation period. To ensure comparable group sizes, randomization was carried out using a computer-generated random number sequence. An impartial clinic nurse who was not involved in patient evaluation or data collection kept the randomization sequence in serial numbered, opaque, sealed envelopes to provide strict allocation concealment. In order to successfully eliminate selection bias, the envelopes were unlocked sequentially only when the patient satisfied all inclusion criteria and provided informed consent.

Exclusion criteria included a positive pregnancy test, prior exposure to any BT serotype, and use of any preventive headache medication within 4 weeks of the baseline start of the trial.

Patients who received 155 U of OnaBT-A were given 5 U in the procerus and each corrugator muscle (one injection site), 10 U in each frontalis muscle (two injection sites), 20 U in each temporalis muscle (four injection sites), 15 U in each occipitalis muscle (three injection sites), 10 U in each cervical paraspinal muscle (two injection sites), and 12.5 U in each trapezius muscle (three injection sites).

Patients who received 200 U of OnaBT-A, the identical procedure that was used to patients who were given 155 U. The temporalis, occipitalis, and cervical paraspinal muscles get an equal injection of the additional 45 U.

A 30-gauge, half inch needle was utilized, and the diluent was Preservative free normal saline with 2 mL/100 U of OnaBT-A. The procedure was brief, typically taking 15 to 30 minutes. The majority of patients describe the injections feeling like tiny pinpricks; however, some discomfort is expected. For breakthrough migraine attacks, the use of acute migraine medication was approved.

At the start of the trial, each group received OnaBT-A as well as after 12 weeks. the following outcome indicators were collected and recorded before the injection at baseline, at weeks 12 and at week 24: the number of migraine attacks (monthly headache frequency), attack severity (as determined by the Global Assessment of Migraine Severity, or GAMS) [8,9], duration of headaches in hours, and disability.

The Migraine Disability Assessment (MIDAS) questionnaire was used to evaluate the disability. It has four grades: I (0–5) indicates little to no disability, II (6–10) indicates mild disability, III (11–20) indicates moderate disability, and IV (21 or more) indicates severe disability [9,10].

Statistical analysis.

IBM SPSS Statistics version 25.0 was used for data management and statistical calculations. The demographic and

baseline clinical features of the patients were summarized using descriptive statistics. Continuous variables were valued using the Independent Samples t-test; categorical variables (Gender, Therapeutic Profile, and Comorbidities) were evaluated using Pearson's Chi-square test. A Repeated Measures ANOVA (or Paired t-test) was performed over the three time points (Baseline, Week 12, Week 24) to evaluate improvement from baseline within each group. The Bonferroni adjustment was used to control Type I error inflating result from numerous evaluations in post-hoc pairs-wise comparisons within groups. The independent sample t-tests and their 95% confidence intervals were used for group comparisons of the various clinical endpoints at weeks 12 and 24. When necessary, a conservative P-value threshold or explicit Bonferroni adjustment was used to ensure the stability of the reported differences. Statistical significance was considered as a two-tailed P-value < 0.05.

Results.

This study comprised a total of 106 patients. Table 1 displays the principal characteristics of individuals. Participants had a mean age of 37.51 ± 9.53 years. The majority of the patients were female (71.6%). There are no statistically significant differences between the OnaBT-A 200 U and OnaBT-A 155 U groups in terms of baseline characteristics. Both groups are well-matched in terms of demographics (age, sex) and clinical baseline characteristics (headache frequency, severity, duration, and disability). Because the groups are well-balanced at the outset, any differences in results after treatment can be attributed to the dosage difference (200 U vs. 155 U) rather than pre-existing differences in the research population.

Measures of clinical efficacy:

By comparing the frequency of migraine days, severity, the mean duration of the headache, and the disability from the headache at zero time and at weeks 12 and 24 of therapy, we were able to determine the effectiveness of each dose of OnaBT-A.

98 individuals completed the 24-week follow-up and were included in the final analysis, while 8 (7.5%) of the 106 randomly assigned patients withdrew, due to the cost aspects of OnaBT-A or adverse effects, Figure 1.

A random sample of eligible individuals who visited the clinic throughout the research enrolment period was used. A post-hoc power analysis revealed that, considering a SD of 2.6 days, an overall sample size of 98 completing patients gives about 80% statistical power ($\beta = 0.20$) with a two-sided level of significance ($\alpha = 0.05$) to detect a minimum clinically significant difference of 1.5 migraine days/ month between the two dose groups. A Per-Protocol (PP) approach was used to conduct statistical analyses for clinical efficacy, carefully examining data from the 98 patients that finished the full 24 weeks follow-up time ($n = 50$ in the 200 U group; $n = 48$ in the 155 U group). patients who withdrew before week 24 ($n = 8$ total) were not included in the longitudinal efficacy analysis because of lacking of their data. This is a limitation with consideration of rigorous intention-to-treat standards.

Both groups experienced a statistically significant decline in frequency of headaches from the baseline to 12 weeks, which maintained or continued at 24 weeks. The group that received 200 U of OnaBT-A showed a decrease from 19.60 ± 2.93 (at baseline) to 16.14 ± 2.34 (after 24 weeks), with a p value of

Table 1. Descriptive data of the patients and the baseline headache characteristics for each group.

Variable	Total (n=106)	OnaBT-A (200 U) (n=56)	OnaBT-A (155 U) (n=50)	P-value*
Gender, n (%)				0.779
- Female	76 (71.7%)	39 (69.6%)	37 (74.0%)	
- Male	30 (28.3%)	17 (30.4%)	13 (26.0%)	
Age (years), Mean $\pm$ SD	37.51 $\pm$ 9.53	37.20 $\pm$ 9.72	37.16 $\pm$ 9.26	0.983
Migraine Onset Age, Mean $\pm$ SD	27.11 $\pm$ 6.68	27.04 $\pm$ 6.75	27.73 $\pm$ 6.85	0.603
Therapeutic Profile, n (%)				
- Beta Blockers	34 (32.1%)	17 (30.4%)	17 (34.0%)	0.692
- Anticonvulsants	48 (45.3%)	26 (46.4%)	22 (44.0%)	0.801
- Antidepressants	52 (49.0%)	30 (53.5%)	22 (44.0%)	0.327
- Other drugs	24 (22.6%)	13 (23.2%)	11 (22.0%)	0.88
Psychiatric Comorbidities, n (%)				
- Clinical Depression	31 (29.2%)	15 (26.8%)	16 (32.0%)	0.555
- Anxiety Disorders	38 (35.8%)	21 (37.5%)	17 (34.0%)	0.707
Baseline Clinical Parameters (mean $\pm$SD)				
Monthly Frequency (days)	19.63 $\pm$ 2.88	19.60 $\pm$ 2.93	19.53 $\pm$ 2.89	0.902
Severity (GAMS score)	5.58 $\pm$ 2.84	5.38 $\pm$ 2.82	5.64 $\pm$ 2.86	0.639
Duration (hours)	59.33 $\pm$ 11.61	58.88 $\pm$ 11.28	58.39 $\pm$ 11.90	0.828
Disability (MIDAS score)	56.57 $\pm$ 18.56	57.66 $\pm$ 18.34	55.18 $\pm$ 17.02	0.474

• U: International Unit, n: number, SD: standard deviation

• P value is significant at 0.05 or less

Table 2. Clinical Outcomes and Treatment Response for the OnaBT-A 200 U Group over 24 weeks.

Outcome Measure	Baseline (Mean $\pm$ SD) (n=56)	12 Weeks (Mean $\pm$ SD) (n=53)	24 Weeks (Mean $\pm$ SD) (n=50)	% Reduction (at 24 Weeks)	P-value*
Monthly Frequency (Days)	19.60 $\pm$ 2.93	16.74 $\pm$ 2.65	16.14 $\pm$ 2.34	17.65%	< 0.05
Headache Severity (GAMS)	5.38 $\pm$ 2.82	3.44 $\pm$ 2.32	3.26 $\pm$ 2.46	39.41%	< 0.001
Duration (Hours)	58.88 $\pm$ 11.28	37.72 $\pm$ 10.21	34.62 $\pm$ 10.67	41.20%	< 0.001
Disability (MIDAS Score)	57.66 $\pm$ 18.34	19.32 $\pm$ 13.86	18.12 $\pm$ 12.96	68.57%	< 0.001

• U: International Unit, SD: standard deviation

• P value is significant at 0.05 or less

Table 3. Clinical Outcomes and Treatment Response for the OnaBT-A 155 U Group over 24 weeks.

Outcome Measure	Baseline (Mean $\pm$ SD) (n=50)	12 Weeks (Mean $\pm$ SD) (n=50)	24 Weeks (Mean $\pm$ SD) (n=48)	% Reduction (at 24 Weeks)	P-value*
Monthly Frequency (Days)	19.53 $\pm$ 2.89	18.23 $\pm$ 2.78	17.94 $\pm$ 2.54	8.14%	< 0.05
Headache Severity (GAMS)	5.64 $\pm$ 2.86	4.22 $\pm$ 2.56	3.94 $\pm$ 2.24	30.14%	< 0.001
Duration (Hours)	58.39 $\pm$ 11.90	44.27 $\pm$ 11.45	41.44 $\pm$ 11.56	29.03%	< 0.001
Disability (MIDAS Score)	55.18 $\pm$ 17.02	22.44 $\pm$ 13.56	20.93 $\pm$ 13.24	62.07%	< 0.001

• U: International Unit, SD: standard deviation

• P value is significant at 0.05 or less

Table 4. Clinical response comparison following 12 and 24 weeks of OnaBT-A treatment with doses of 200 U and 155 U.

Outcome Measures	Time Point	OnaBT-A 200 U (Mean $\pm$ SD)	OnaBT-A 155 U (Mean $\pm$ SD)	Mean Difference (95% CI)	P-value*
Monthly Frequency (Days)	12 Weeks	16.74 $\pm$ 2.65	18.23 $\pm$ 2.78	-1.49 (-2.54, -0.44)	0.006
	24 Weeks	16.14 $\pm$ 2.34	17.94 $\pm$ 2.54	-1.80 (-2.76, -0.84)	<0.001
Headache Severity (GAMS)	12 Weeks	3.44 $\pm$ 2.32	4.22 $\pm$ 2.56	-0.78 (-1.73, 0.17)	0.109
	24 Weeks	3.26 $\pm$ 2.46	3.94 $\pm$ 2.24	-0.68 (-1.61, 0.25)	0.155
Duration (Hours)	12 Weeks	37.72 $\pm$ 10.21	44.27 $\pm$ 11.45	-6.55 (-10.77, -2.33)	0.002
	24 Weeks	34.62 $\pm$ 10.67	41.44 $\pm$ 11.56	-6.82 (-11.25, -2.39)	0.003
Disability (MIDAS Score)	12 Weeks	19.32 $\pm$ 13.86	22.44 $\pm$ 13.56	-3.12 (-8.46, 2.22)	0.25
	24 Weeks	18.12 $\pm$ 12.96	20.93 $\pm$ 13.24	-2.81 (-8.05, 2.43)	0.27

• U: International Unit, SD: standard deviation

• P value is significant at 0.05 or less

Table 5. Comparison the adverse events of OnaBT-A treatment with doses of 200 U and 155 U.

Adverse Event (AE)	OnaBT-A 200 U (n = 56)	OnaBT-A 155 U (n = 50)	P-value*
Patients with one or more one AE, n (%)	10 (17.8%)	6 (12.0%)	0.584
Injection site pain/tenderness	4 (7.1%)	3 (6.0%)	0.822
Neck pain / muscle stiffness	3 (5.4%)	2 (4.0%)	0.741
Transient drooping eyelid	2 (3.6%)	1 (2.0%)	0.627
Muscle weakness (facial/cervical)	1 (1.8%)	0 (0.0%)	0.342
Discontinuation due to AEs, n (%)	3 (5.4%)	1 (2.0%)	0.621

*Fisher's Exact Test / Chi-square test significance at $P \leq 0.05$.

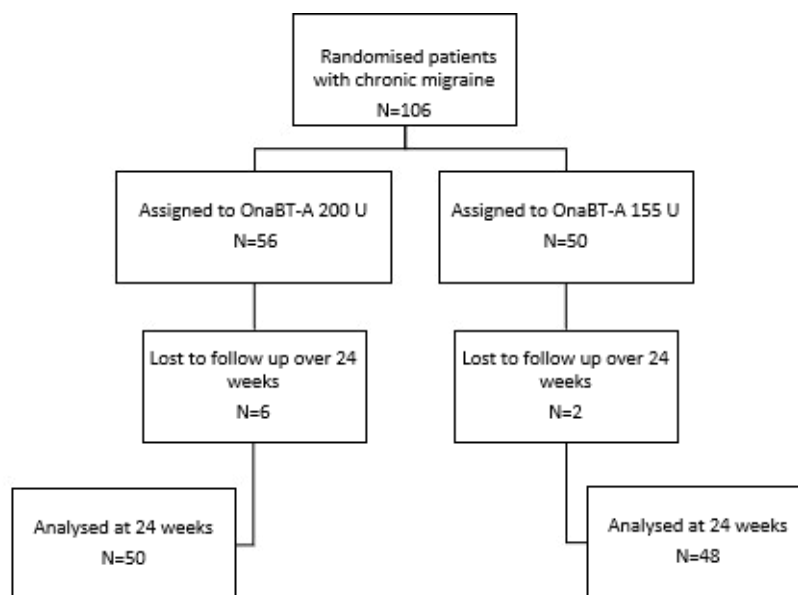


Figure 1. Flow diagram demonstrating the randomization and follow-up of both groups of patients with chronic Migraine treated with OnaBT-A 200 U and 155 U.

<0.05 , suggesting substantial statistical significance. The group who received 155 U, showed similar decreases (from 19.53 ± 2.89 to 17.94 ± 2.54), with p-values indicating significance (<0.05).

The severity of headaches decreased significantly across both groups throughout the study period. The group that received 200 U of OnaBT-A revealed a reduction from (5.38 ± 2.82 to 3.26 ± 2.46 over 24 weeks) (p-value <0.001), whereas the other group showed comparable results with significant reductions. Similar patterns observed in duration of headache in all therapeutic approach groups resulting in significant decreases from the baseline over the entire times of evaluation (p-value <0.001). For example, the group that received 200 U and 155 U showed reduction in the headache duration (from 58.88 ± 11.28 to 34.62 ± 10.67 hours) and (from 58.39 ± 11.90 to 41.44 ± 11.56), respectively. Both groups demonstrated significant decreases in MIDAS ratings, indicating reduction in headache disability, the group that received 200 U was remarkably effective, it showed decreasing of MIDAS score from 57.66 to 18.12 (p-value <0.001), and the disability Grade was Severe with a baseline score of 55.18, fell to 20.93 by 24 weeks for patients those given 155 U.

The most remarkable finding is that the 200 U dosage is much more effective than the 155 U dose in lowering the number of headache days and the overall duration of episodes. At 24 weeks, the 200 U group experienced an average of 16.14 headache

days versus 17.94 in the 155 U group ($P < 0.001$). Similarly, the higher-dose group experienced significantly reduced headache duration at both milestones ($P < 0.01$), indicating that greater dosages may help headache episodes end more quickly. From 12 to 24 weeks, the effectiveness gap between 200 and 155 U dosages expanded or remained consistent in terms of frequency and duration. This shows that the higher dose (200 U) has a longer-lasting and more effective preventive effect than the regular 155 U dose.

About headache severity or disability (MIDAS ratings), there was no statistically significant difference between the two dosages. Although 200 U decreases the "quantity" of headache days, the "quality" of relief (pain intensity and functional impact) is similar between the two regimens, as both groups saw an overall decrease in headache-related disability. According to Post Hoc analysis, no significant difference in all groups (p-value ranged between 0.7 and 0.9) is observed between the two post treatment time points for any of the outcome measures, indicating similar effectiveness at those two time points. This suggests that by week 12, treatment efficacy is established and is constant until week 24.

These conclusions are supported by the use of 95% Confidence Intervals. There is a high degree of confidence in the superiority of the 200 U dose because the ranges for frequency and duration do not contain zero. On the other hand, the intervals for severity and MIDAS contain zero, indicating that sample variability

rather than the dosage itself may be the cause of the observed variations in those metrics.

OnaBT-A proved generally considered well-tolerated in both dosage groups; however, 4 patients (3.8% of the initial sample) explicitly stopped the trial due to adverse events: three patients in the 200 U group and one patient in the 155 U group ($P = 0.621$, showing not a statistically significant distinction in overall discontinuation safety profiles). Neither group experienced any systemic botulinum toxicity or severe adverse event (AE). The comparison occurrence of adverse events across the two dosage groups is shown in Table 5.

Discussion.

CM is a complicated neurological illness characterized by cognitive, sensory, physical and emotional comorbidities that require to be prevented to avoid the patients' disabilities [11].

The PREEMPT-1 and PREEMPT-2 studies established class one evidence for OnaBT-A. Individuals with CM, aged 18 to 65, who did not have persistent headache, were randomly selected to receive 155–195 U of OnaBT-A at 31 sites across the head and neck. 1384 individuals were randomly assigned to receive either a placebo or OnaBT-A throughout the experiments. According to pooled analysis, the number of research participants who achieved at least a 50% reduction in monthly migraine days was 47.1% (placebo 35.1%), and monthly headache days were shown to be significantly reduced by 8.4 with 24 weeks of OnaBT-A compared to 6.6 with the placebo [3,12].

Nine studies [13–21] found that botulinumtoxin decreased the frequency of CM in patients. Furthermore, three studies of them [13,20,21] demonstrated that botulinumtoxin lessened the severity of pain in CM patients.

Evaluating the long-term effectiveness of OnaBT-A in treating CM done by the REPOSE research, an open-label study involving 641 participants. It showed that after 24 months, monthly headache days decreased from a mean 20.5 at baseline to 7.4, and quality of life parameters improved in parallel [14].

There is some controversy about the best effective dose of OnaBT-A for CM prevention. In the PREEMPT studies, the authors did not assess the efficacy of different doses of OnaBT-A, but rather compared OnaBT-A therapy at doses varying from 155 to 195 U to a placebo [22].

In a randomized clinical experiment, Silberstein et al. contrasted various OnaBT-A dosages (i.e., 225, 150, and 75 U) with a placebo. The frequency of headaches was significantly reduced in patients who got 150 or 225 U of OnaBT-A after 240 days. For the group that received 75 U of OnaBT-A, this difference didn't reach statistically significant levels [23].

A different trial involved enrolling patients who did not respond to the standard OnaBT-A therapy (mean dose $\pm$ SD: 170 ± 10 U) to receive 6 rounds of 200 U of Incobotulinum toxin followed by 2 rounds of 200 U of OnaBT-A. Higher dosages of botulinumtoxin A therapy demonstrated long-lasting improvements in the frequency of monthly headache episodes and pain severity in that trial [24]. Similarly, in limited research on Russian women, 195 U of OnaBT-A were better than 155 U [25].

In the current study, all headache outcome variables (frequency, severity, duration, and disability) showed significant

improvements with both treatment regimens (200 U and 155 U dosages of OnaBT-A). The most significant gains were consistently seen with the higher dose. These results imply that both OnaBT-A dosages are useful in controlling headache symptoms and lowering the resulting disability.

Notice that the greatest improvement occurs between baseline and 12 weeks. The progression continues between 12 and 24 weeks, albeit at a slower pace. This is a common "tapering" pattern in clinical therapies where the initial reaction is the strongest.

In pilot research conducted in Turkey in 2013, the therapeutic impact of OnaBT-A on headache was examined in 30 individuals with a diagnosis of migraine. The patients' mean MIDAS value at the initial visit was 59.5 ± 24.3 (number=30) and at week twelve was 23 ± 20.6 (number=12) when injections were administered again. The mean score at the 24-week was 20.4 ± 20.1 (number=5). the variance between the first and second MIDAS scores was 61.1%, and was 65.72% between the first and third MIDAS scores [26].

The mean MIDAS score in our study decreased significantly in both groups. The group that received 200 U of OnaBT-A had already decreased by 66.49% by 12 weeks. At the 24-week mark, the improvement persisted somewhat, resulting in a total decrease of 68.57% from the baseline. A significant clinical success is a decrease from 57.66 (Grade IV: Severe Disability) to 18.12 (Grade III: Moderate disability). The group that received 155 U had dropping of MIDAS score about 62.07%. The disability Grade was IV (Severe) with a baseline score of 55.18, The score fell to 20.93 by 24 weeks, which is close to Grade III (Moderate Disability). This implies that the patient's capacity to work and carry out daily tasks has significantly improved, even if they are still having headaches.

The results of comparing the effectiveness of OnaBT-A alone at the two doses indicate that the 200 U dose of OnaBT-A significantly improved monthly headache frequency and headache duration when compared to the 155 U dose according to statistically significant p-values at both time points. Despite the improvement in severity that favored the higher dose, the differences were not statistically significant. Furthermore, there were no significant differences in disability scores between both doses. According to these results, the 200 U dose of OnaBT-A seems to be more effective in lowering the frequency and headaches duration, which could make it a good choice for patients seeking relief from chronic headaches. However, when considering treatment choices, clinicians should also take into account the absence of distinctions in headache severity and disability between two doses.

These data suggest a dose-dependent response to OnaBT-A therapy, which is consistent with the findings of Zandieh, A., and Cutrer, F.M., who reported that three rounds of OnaBT-A 200 U followed three rounds of 150 U, resulting fewer severe and total headache [22].

The open-label trial design is an important factor to take into account when assessing these results. The possibility of a larger expectancy of benefit (a classic placebo response) in the high-dose (200 U) group cannot be ruled out. This is especially important for patient-reported, subjective outcomes like functional disability (MIDAS) and headache severity

(GAMS). It's interesting to note, nevertheless, that there were no statistically significant changes in the headache severity and disability scores at 12 or 24 weeks between the 200 U and 155 U groups. Only the objective criteria, such as the total duration and quantitative frequency of headache days, were shown to exhibit significant variations. This finding supports the clinical validity of our targeted results by indicating that, although performance or response bias may generally overestimate subjective benefits in open-label trials, it did not specifically improve subjective "quality" of pain relief in the higher-dose group.

The mechanisms of OnaBT-A in reducing headache in CM achieved by reducing activation of peripheral pathways primarily and central pathways as a secondary result. This mechanism include: (a) its action on peripheral nerve endings to interfere with precise events in the synaptic vesicle cycle that fuse to the cell membrane normally and are recycled. This interfering is occurring by increasing of nociceptive activation threshold by decreasing neurotransmitters and neuropeptides (eg, CGRP) circulating levels; (b) down regulation of (transient receptor potential cation channel subfamily V member 1 (TRPV1)) receptors on unmyelinated C-fiber nociceptors in trigeminal ganglion subsequent peripheral OnaBT-A injections into the muscles of face; (c) reduction dorsal horn neurons activation and expression of Nitric oxide synthase in the CNS after OnaBT-A injections; (d) reduction the number of synapses and dendrites in central sensory pathways, which was also associated with changes in cell body shape and nucleolus. It is currently believed that synaptic plasticity, central sensitization, and other CNS alterations linked to OnaBT-A injections are secondary to declining peripheral input in light of new evidence disproving OnaBT-A trans-synaptic transfer [27].

Both doses (155 and 200 U) can block the principal pain neurotransmitters (CGRP and Substance P) at the injection site. When the toxic substance reduces the pain signal, stronger stimulation is required. However, if the stimulus is strong enough to overcome this higher threshold, the subsequent pain signal activates the same inflammatory pathways that were previously partially blocked by the lower dose. This is known as the potential therapeutic ceiling effect, in which raising the dose effectively raises the activation threshold and reduces the frequency of nerve firing rather than affecting the severity of CM.

According to previous studies, patients with chronic migraines often tolerate OnaBT-A extremely well; rates of treatment discontinuation owing to side effects have been observed to range from 1.4% to 3.8%. This implies that OnaBT-A can be administered to the majority of patients without having a major negative influence on their adherence to therapy.

However, other preventative migraine medications have a far greater risk of side effect-related discontinuation (12.7%). This suggests that these alternative treatments may cause more unbearable adverse effects for patients [28].

Four patients in current study stopped taking OnaBT-A because of adverse effects. This rate is much lower than the discontinuation rates observed with other preventive medications and falls within the lower range of previously reported tolerability for OnaBT-A.

In summary, these findings illustrate the significance of OnaBT-A dosage in the management of chronic headaches and

offer crucial data to inform clinical decisions. While the 155 U dose gives adequate relief of pain intensity for many, the 200 U dose should be seen as a Frequency-Targeted Strategy. It is specifically intended for patients with a high burden of headache days who require a more aggressive reduction in attack occurrence rather than only attack intensity. The possible advantages and best practices for using this medicine to treat CM will be better clarified by more research.

The main limitation of this research is that there was no placebo arm and the researchers were not blinded. As a result, researchers were vulnerable to biases regarding the new intervention arms.

Conclusion.

Overall, the study shows that OnaBT-A significantly lessen the headache burden. The efficacy of this treatment approaches for CM patients is confirmed by the statistically significant p-values' consistency across both groups. It concludes that administering 200 U of OnaBT-A, significantly reduce the frequency and duration of headaches when compared to lower dosages. It suggests that escalation to 200 U be considered for those who do not obtain satisfactory frequency control and do not achieve adequate relief with the standard 155 U dose. The promising outcomes suggest a need for further studies into long-term effects and evaluation of higher dosages or alternative preventive treatment regimens.

Acknowledgment.

I want to sincerely thank all the study participants for their commitment. I also express my gratitude to my clinic team for their efforts during the study. Special appreciation to college of medicine in Ninevah University for their support.

Conflicts of Interest.

The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

Funding.

The research did not receive any financial support from any institution.

Ethics Statements.

This study was approved by the college of medicine Ethics Committee in Ninevah University and was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Informed consent was obtained from all participants prior to their inclusion in the study.

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Аннотация:

Введение: Мигрень — распространённое неврологическое заболевание; её можно классифицировать как эпизодическую или хроническую. При хронической мигрени (ХМ) одним из методов лечения, показавших свою эффективность, является онаботулинотоксин А (ОнаБТ-А).

Цель исследования: подтвердить дозозависимый эффект лечения ОнаБТ-А при ХМ.

Материалы и методы: Данное проспективное рандомизированное сравнительное исследование было проведено в частной неврологической клинике в Мосуле, Ирак. В исследовании приняли участие 106 пациентов, соответствующих диагностическим критериям ХМ. Были сформированы две группы пациентов. Первая группа получила 200 ЕД ОнаБТ-А путем местной инъекции, вторая группа — 155 ЕД. Каждая группа получала ОнаБТ-А в начале исследования, а также через 12 недель. Показатели результатов, включающие: ежемесячную частоту головных болей, тяжесть приступов, продолжительность головных болей и степень инвалидности, были собраны и зарегистрированы на исходном уровне, на 12-й и 24-й неделях.

Результаты: все переменные, характеризующие головную боль, показали значительное улучшение при обоих режимах лечения. Эффективность этих методов лечения подтверждается статистически значимыми значениями *p*,

согласованными в обеих группах. Наиболее значительные улучшения наблюдались в первой группе при более высокой дозе.

Выводы: Исследование показало, что введение 200 ЕД Онаботулинотоксина А значительно снижает частоту и продолжительность головных болей по сравнению со 155 ЕД. Рекомендуется рассматривать эту дозировку для пациентов, у которых не достигается адекватное облегчение при 155 ЕД Онаботулинотоксина А. Обнадеживающие результаты указывают на необходимость дальнейших исследований долгосрочных эффектов и оценки более высоких доз.

Ключевые слова: хроническая мигрень, онаботулинотоксин А, дозозависимая эффективность, профилактическое лечение.

რეზიუმე.

შესავალი:

შაკიკი გავრცელებული ნევროლოგიური მდგომარეობაა; მისი კლასიფიცირება შესაძლებელია როგორც ეპიზოდური, ასევე ქრონიკული. ქრონიკული შაკიკის (CM) დროს ერთ-ერთი თერაპია, რომელიც ეფექტურია, არის ონაბოტულინუმტოქსინი A (OnaBT-A). კვლევის მიზანი: დადასტურდეს, რომ OnaBT-A მკურნალობის ეფექტი დამოკიდებულია დოზაზე CM-ის სამკურნალოდ.

მასალა და მეთოდები: ეს პერსპექტიული, რანდომიზებული, შედარებითი კვლევა ჩატარდა ერაყის ქალაქ მოსულში მდებარე კერძო ნევროლოგიურ კლინიკაში. კვლევაში მონაწილეობდა სულ 106 პაციენტი, რომლებიც აკმაყოფილებდნენ CM-ის

დიაგნოსტიკურ კრიტერიუმებს. ჩამოყალიბდა პაციენტების ორი ჯგუფი. პირველმა ჯგუფმა მიიღო OnaBT-A-ს 200 ერთეული ადგილობრივი ინექციით, მეორე ჯგუფმა - 155 ერთეული. თითოეულმა ჯგუფმა მიიღო OnaBT-A კვლევის დასაწყისში, ასევე 12 კვირის შემდეგ. შედეგის ინდიკატორები, რომლებიც მოიცავს: თავის ტკივილის ყოველთვიურ სიხშირეს, შეტევის სიმძიმეს, თავის ტკივილის ხანგრძლივობას და ინვალიდობას, შეგროვდა და ჩაიწერა საწყის ეტაპზე, მე-12 და 24-ე კვირას.

შედეგები: თავის ტკივილის ყველა შედეგის ცვლადმა აჩვენა მნიშვნელოვანი გაუმჯობესება ორივე მკურნალობის რეჟიმის დროს. ამ მკურნალობის მიდგომების ეფექტურობა დასტურდება სტატისტიკურად მნიშვნელოვანი p-მნიშვნელობების თანმიმდევრულობით ორივე ჯგუფში. ყველაზე მნიშვნელოვანი გაუმჯობესება დაფიქსირდა პირველ ჯგუფში, უფრო მაღალი დოზით.

დასკვნები: კვლევა ასკვნის, რომ OnaBT-A-ს 200 ერთეულის მიღება მნიშვნელოვნად ამცირებს თავის ტკივილის სიხშირეს და ხანგრძლივობას 155 ერთეულთან შედარებით. რეკომენდებულია ამ დოზის გათვალისწინება იმ პაციენტებისთვის, რომლებიც ვერ აღწევნენ საკმარის შედეგს OnaBT-A-ს 155 ერთეულით. იმედისმომცემი შედეგები მიუთითებს გრძელვადიანი ეფექტების შემდგომი კვლევების საჭიროებაზე და უფრო მაღალი დოზების შეფასებაზე.

საკვანძო სიტყვები: ქრონიკული შაკიკი, ონაბოტულინის ტოქსინი A, დოზაზე დამოკიდებული ეფექტურობა, პრევენციული მკურნალობა.