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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии
საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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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.

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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.

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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. Корректур 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 საქურაღებოლ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დაიცვათ 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, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შედეგის 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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INFLUENCE OF ADDING ZINC ARGINYLE-GLYCINATE TO IMPROVE EFFICACY OF BIOREGULATORY PEPTIDES OF THE PROSTATE GLAND IN TREATMENT OF PATIENTS WITH IMPAIRED SPERM PARAMETERS

Rybalov M.A.¹, Borovets S.Yu¹, Petlenko S.V.², Krasnov A.A.³, Apryatina V.A.⁴.

¹*Pavlov First Saint Petersburg State Medical University, Research Institute for Surgery and Emergency Medicine, Research Center of Urology.*

²*Golikov Research Clinical Center of Toxicology under the Federal Medical-Biological Agency.*

³*The Herzen State Pedagogical University of Russia, Ministry of Science and High Education of the Russian Federation.*

⁴*Saint-Petersburg State University, Institute of Translational Biomedicine, Neurobiology and Molecular Pharmacology Laboratory, Saint-Petersburg, Russian Federation.*

Abstract.

The drug Prostatilen® AC, rectal suppositories were developed on the basis of the previously registered medicine containing bioregulatory peptides of the prostate gland - Prostatilen® rectal suppositories, 3 mg, from whom it differs by the addition of active pharmaceutical ingredient zinc arginyle-glycinate dihydrochloride (ZAG). The aim of this study was to analyze the positive effect of adding ZAG to the drug in patients with impaired spermatogenesis.

A total of 98 men aged 25-45 years (an average of 35.2±4.3 years) with a verified diagnosis of chronic abacterial prostatitis and related reproductive dysfunctions in the phase III, randomized, multicenter, open-label clinical trial was examined. The duration of participation of patients in the study was 14–16 days, the screening period was 2–3 days, the duration of therapy was 10 days, and the final examination was 2–3 days. A study group (n=49) received therapy with Prostatilen AC once daily, a control group (n=49) had Prostatilen once daily. All patients underwent conventional semen analysis before and after treatment. The obtained parameters were compared.

During the analysis of the average statistical data in the comparison groups, it was found that treatment with Prostatilen AC leads to an increase in the total population of motile spermatozoa (cells A + B + C) by 14.3%, and the reference drug Prostatilen contributes to an increase in this indicant by 4.1% compared with the results of a screening examination with significantly higher efficiency in increasing the relative count of spermatozoa with a fast progressive motility (After therapy Prostatilen/Prostatilen AC p=0.0004). Prostatilen AC showed significantly higher efficiency in terms of increasing the count of normal forms of spermatozoa in the ejaculate than the reference drug Prostatilen (After therapy Prostatilen/Prostatilen AC p=0.0118). In patients who received the drug Prostatilen AC the number of abnormal forms of spermatozoa decreased by 12.4% (After therapy – 55.57%), and in the comparison group (drug Prostatilen) by 6.5% (After therapy – 58.90%) with significant decrease in forms of abnormal spermatozoa with head, acrosome, or neck pathology for Prostatilen AC compared to control.

Prostatilen AC compared to Prostatilen had a statistically significant and clinically significantly superior efficacy in relation to initially impaired sperm parameters (improve of sperm motility, restoration of morphologically normal sperm,

decrease in forms of abnormal spermatozoa with head, acrosome or neck pathology). This drug could be recommended to use in the treatment of patients in whom chronic prostatitis occurs with concomitant disorders of sexual and reproductive functions.

Key words. Impaired spermatogenesis, zinc arginyle-glycinate, bioregulatory peptides of the prostate gland, chronic prostatitis.

Introduction.

It has been shown that zinc plays a significant role in the male reproductive system [1-4]. The highest concentrations of zinc are found in semen and prostate secretions. Prostate diseases and concomitant sexual and reproductive disorders are zinc-deficient conditions [5]. Against the background of zinc deficiency, there is a delay in sexual development in boys and a decrease in fertility in men [6]. Zinc deficiency leads to a decrease in testicular function, their atrophy, a decrease in the production of sperm, testosterone, and a decrease in potency in men. It has been suggested that Zinc acts as an important anti-inflammatory factor and that it is involved in the sperm's oxidative metabolism [6]. Zinc concentration is high in the seminal fluid and has a multifaceted role in the sperm's functional properties. Zinc ion has been linked with key events in the acquisition of fertilization ability by spermatozoa, including motility, capacitation and acrosomal exocytosis [1].

Arginine reduces the growth of pathogenic microflora, participates in spermatogenesis, improves erectile function, has a significant regulatory effect on the functions of the genitourinary system; ornithine formed from arginine is a precursor of spermine and spermidine [7-9].

Inclusion in addition to the regulatory peptides of the prostate composition of the substance L-arginine (100 mg) and zinc (23 mg) in the form of zinc arginyl-glycinate dihydrochloride (ZAG) active pharmaceutical ingredient (API) made it possible to develop Prostatilen AC drug based on Prostatilen preparation and expand the scope of this medicinal product, using it for the treatment of patients with chronic abacterial prostatitis with impaired reproductive function.

Preclinical studies of Prostatilen AC showed positive results in animal experimental model of male infertility (pathozoospermia) [10] as well as a series of clinical studies [11-14].

The aim of this study was to analyze the positive effect of adding ZAG to the drug in patients with impaired spermatogenesis.

Materials and methods.

A total of 98 men aged 25-45 years (an average of 35.2±4.3 years) with a verified diagnosis of chronic abacterial prostatitis and related reproductive dysfunctions were examined. Inclusion criteria were chronic genitourinary pain in the absence of any infection localized to the prostate gland employing standard methodology with presence of any impaired sperm parameters in semen analysis and erectile dysfunction. Exclusion criteria were intolerance to at least one of the components of the study drugs, infectious or inflammatory diseases, concomitant diseases in the stage of decompensation requiring drug therapy. All patients signed the established informed consent form to participate in the clinical trial. The present clinical trial was carried out in accordance with the principles of the Declaration of Helsinki, the ICH GCP and local ethics committee.

The patients were treated and examined in an outpatient setting at 2 specialized research centers. The duration of participation of patients in the study was 14–16 days, the screening period was 2–3 days, the duration of therapy was 10 days, and the final examination was 2–3 days. A study group (n = 49) received therapy with Prostatilen AC once daily, a control group (n = 49) had Prostatilen once daily. Patients did not receive any other therapy during the treatment period. All patients underwent conventional semen analysis before and after treatment. The obtained parameters were compared.

The investigated drug Prostatilen® AC, rectal suppositories (JSCo Cytomed, Russia) composed of prostate extract (0.03 g) and zinc arginyle-glycinate dihydrochloride (0.18 g as zinc arginyle-glycinate). API zinc arginyle-glycinate dihydrochloride (ZAG; JSCo Cytomed, Russia) contains L-arginine (55,4%), glycine (23,7%) and zinc (20,9%) in form of chelate complex.

The comparison drug Prostatilen® rectal suppositories, 3 mg (JSCo Cytomed, Russia) contain only prostate extract (0.03 g or 3 mg as prostatic peptides).

The analysis of the obtained data was carried out using the IBM SPSS Statistics program 22. In order to test the significance of differences between the samples, Student's t-test was calculated (for paired and independent samples with a normal distribution), as well as the Wilcoxon W-test for paired and Mann-Whitney U-test for independent samples with a non-normal distribution. The normality of distribution in the samples was assessed using the Kolmogorov–Smirnov z-test. The applied significance threshold was taken equal to 95%. The level of achievement of the null statistical hypothesis was $p \geq 0.05$.

Sperm motility grading:

Grade A – rapid progressive motility

Grade B – slow progressive motility

Grade C – Non-progressive motility

Grade D – Immotility

Results.

During the analysis of the average statistical data in the comparison groups, it was found that the study drug Prostatilen AC leads to an increase in the total population of motile spermatozoa (cells A + B + C) by 14.3%, and the comparison drug Prostatilen contributes to an increase in this indicator by 4.1% compared with the results of a screening examination. To assess the level of reproductive activity, subpopulations

of spermatozoa with progressive motility (cells A + B) are of the greatest importance. After the treatment, the number of spermatozoa with progressive motility in the control group (Prostatilen) increased by 8.3% (Screening/After therapy - 47.7/51.7), and in the comparison group (Prostatilen AC) by 20.9% (Screening/After therapy - 43.3%/52.4%) and reached the normal values of this indicator. Intragroup differences between the screening and final study of the ejaculate in terms of the count of cells with fast (cells A) and slow (cells B) progressive motility were statistically significant (Screening/After therapy A and B Prostatilen $p=0.0284$ and $p=0.0404$, respectively; Screening/After therapy A and B Prostatilen AC $p<0.0001$ and $p=0.0009$, respectively) (Figures 1a, 1b). During the statistical analysis of the results of the study, it was found that the study drug Prostatilen AC, in comparison with the reference drug (Prostatilen) shows significantly higher efficiency – 3% difference in increasing the relative count of spermatozoa with a fast progressive motility (After therapy Prostatilen/ Prostatilen AC $p=0.0004$) (Figure 1a).

An increase in the relative count of spermatozoa with progressive motility led to a decrease in the percentage of cells with non-progressive motility (C cells) and immobile forms (D cells) in the ejaculate for both groups. Statistical analysis of the percentage of immobile cells during treatment with study drugs showed that both drugs contributed to a significant decrease in this cell population compared with the results of the screening (Screening/After therapy Prostatilen $p=0.0096$; Screening/After therapy Prostatilen AC $p=0.0008$) (Figures 1c, 1d). Both drugs showed similar efficacy in reducing from screening to end of therapy the population of immobile spermatozoa, from 31.75 to 27.10% for Prostatilen and from 33.90 to 29.31% for Prostatilen AC with absence of significant differences between comparison groups.

During the initial examination, the percentage of normal forms of spermatozoa in the comparison groups was reduced and amounted to 38.69% (Prostatilen group) and 32.92% (Prostatilen AC group) respectively (Figure 2). After treatment with the study drugs in both groups, a significant increase in the relative count of normal spermatozoa was noted (Screening/After therapy Prostatilen $p<0.0001$; Screening/After therapy Prostatilen AC $p<0.0001$) – 42.2% and 43.12%, respectively. The drug Prostatilen AC showed significantly higher efficiency in terms of increasing the count of normal forms of spermatozoa in the ejaculate than the reference drug Prostatilen as evidenced by the presence of statistically significant differences between comparison groups (After therapy Prostatilen/Prostatilen AC $p=0.0118$) (Figure 2).

During the initial examination (Screening), the relative number of abnormal spermatozoa in the comparison groups was almost the same (62.47% in the main group - the drug Prostatilen AC and 62.78% in the control group - the drug Prostatilen). Treatment with the study drugs revealed a similar trend of a decrease in the overall population of abnormal spermatozoa. In patients who received the drug Prostatilen AC rectal suppositories, the number of abnormal forms of spermatozoa decreased by 12.4%, and in the comparison group (drug Prostatilen) by 6.5%.

The registered drug (ProstatilenAC) and the reference drug (Prostatilen) significantly reduced the percentage of cells from

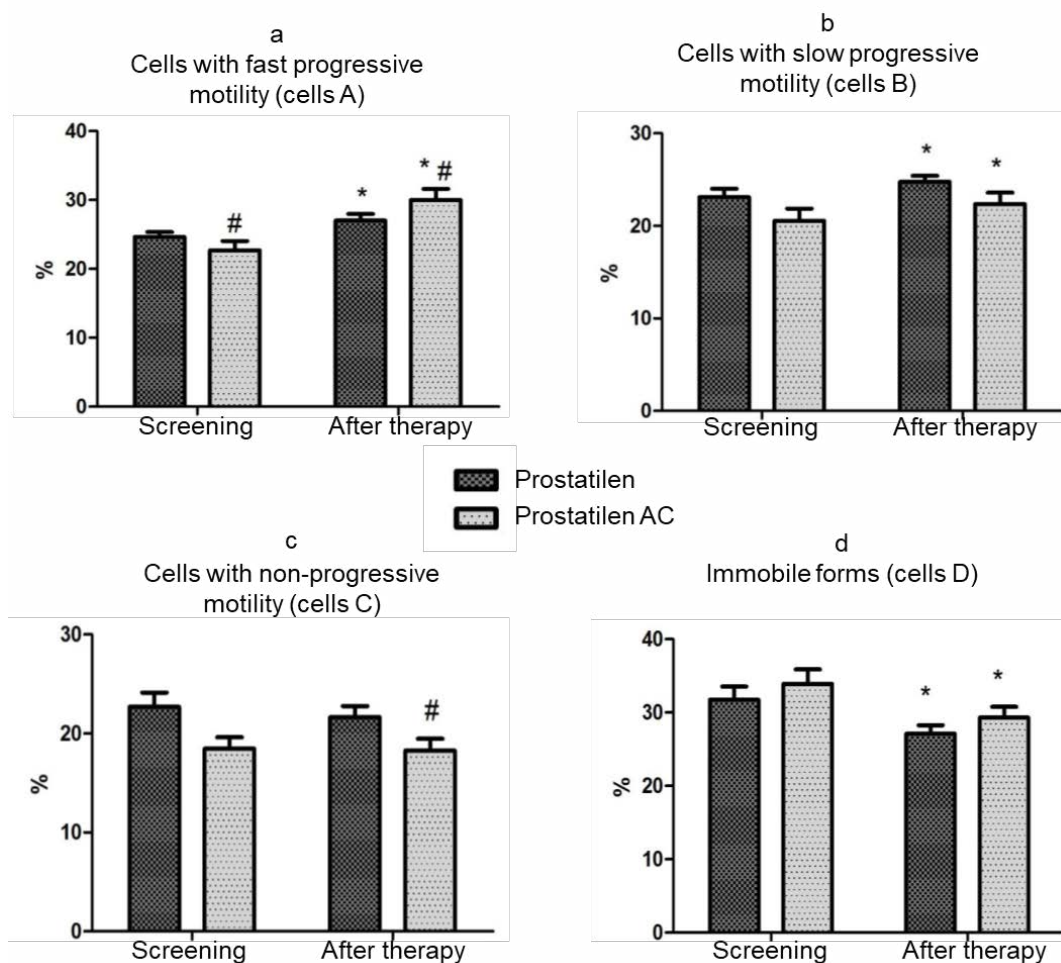


Figure 1. Change in relative sperm count with fast (a) and slow (b) progressive motility, non-progressive motility (c) and immobile forms (d) in the comparison groups before treatment (Screening) and 2-3 days after treatment drugs Prostatilen and Prostatilen AC.

*- $p < 0.05$ compared with screening results, #- $p < 0.05$ compared with Prostatilen after therapy.

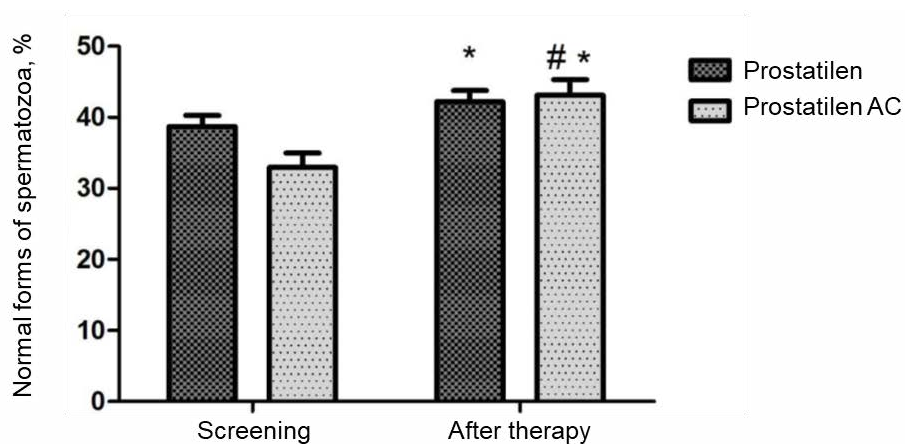


Figure 2. Change in the relative count of normal spermatozoa in the comparison groups during treatment with study drugs.

*- $p < 0.05$ compared with screening results, #- $p < 0.05$ compared with Prostatilen after therapy.

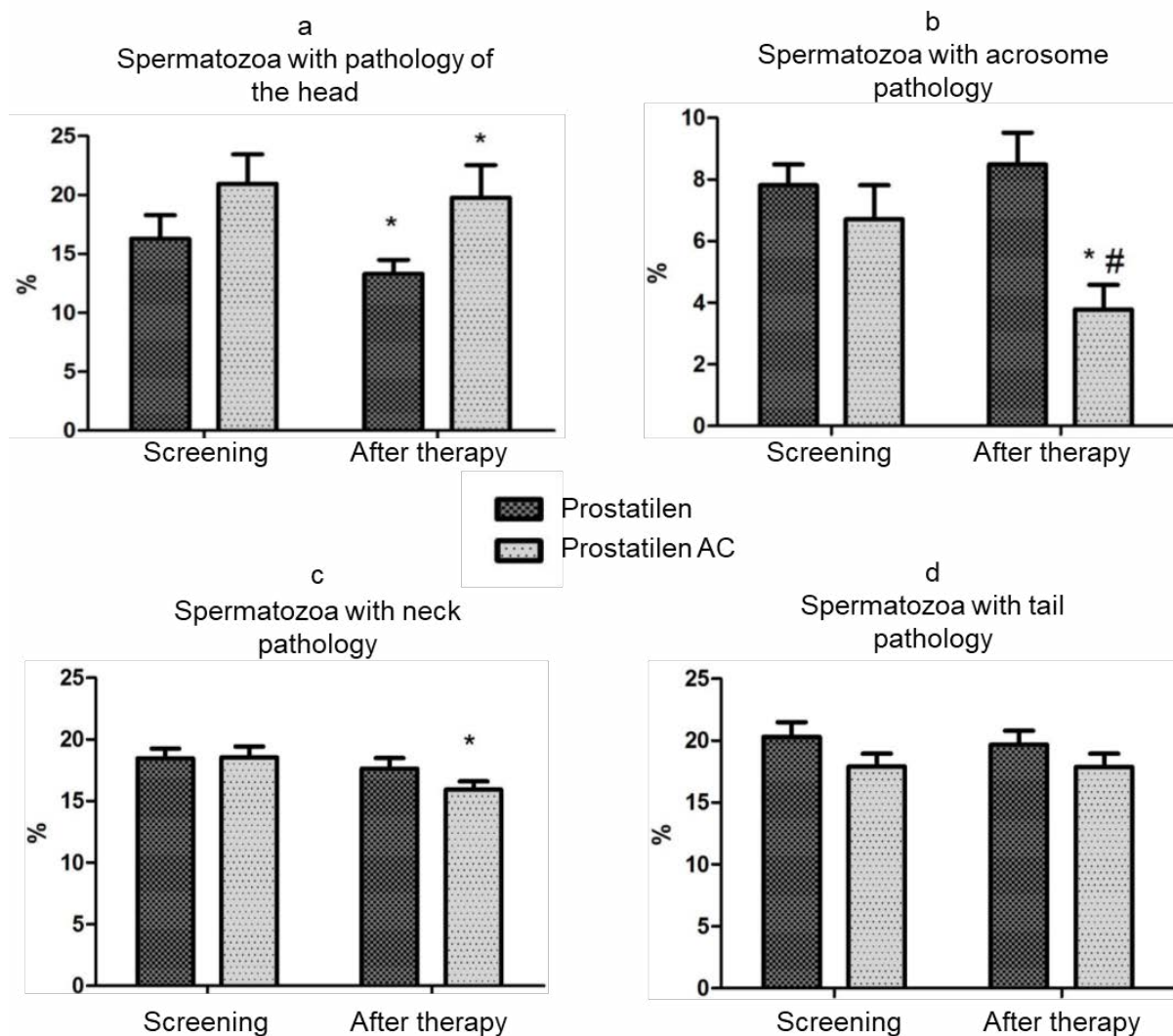


Figure 3. Change in the relative count of spermatozoa with the pathology of the head (a), acrosome (b), neck (c), tail (d) in the comparison groups during treatment with study drugs.

*- $p < 0.05$ compared with screening results

#- $p < 0.05$ compared with Prostatilen after therapy.

head pathologies after course use (Screening/After therapy Prostatilen $p=0.0096$; Screening/After therapy Prostatilen AC $p=0.0008$). There were no significant intergroup differences in the percentage of spermatozoa with head pathology during the final study of the ejaculate (Figure 3a).

During the analysis of the clinical trial data, it was found that the drug Prostatilen did not have a significant treatment effect on the relative count of spermatozoa with acrosome pathology (Screening/After therapy $p=0.9084$) (Figure 3b). The use of the study drug Prostatilen AC contributed to a statistically significant decrease in the population of spermatozoa with acrosome pathology in the ejaculate of patients of the main group during the final study compared with the results of screening (Screening/After therapy $p < 0.0001$). Statistical analysis of data from the baseline (Screening) showed that in terms of the relative count of spermatozoa with acrosome pathology in the ejaculate, the comparison groups did not have statistically significant differences and were representative

(Prostatilen group - 7.8%, Prostatilen AC group - 6.7%, $p=0.0530$). Statistical evaluation of the intergroup dynamics of the count of cells with pathological changes in the acrosomal region, during treatment with the studied drugs, showed that Prostatilen AC appeared significantly more pronounced efficacy (3.8%) than the reference drug Prostatilen (8.5%) contributing to the reduction of this population of pathological spermatozoa (After therapy Prostatilen/ Prostatilen AC $p < 0.0001$), which may serve as indirect evidence of an increase in reproductive function (Figure 3b).

According to the average value of the relative count of spermatozoa with neck pathology during the screening examination, the groups did not have significant differences. In the treatment with the study drugs in the comparison groups, similar trends to a decrease in the percentage of spermatozoa with pathological changes in the neck in the ejaculate were revealed. The dynamics of the relative count of cells with pathology of the neck, during the treatment with the drug Prostatilen AC

was characterized by a significant decrease in this population of spermatozoa (Screening - 18.55% / After therapy - 15.92%, $p < 0.0001$) at the final examination patients, compared with baseline data (Figure 3c). In the control group (Prostatilen), the decrease in the count of this cell population was less pronounced (Screening - 18.40% / After therapy -17.60%) and was not significant ($p=0.13$). Registered drug Prostatilen AC showed greater efficiency in reducing spermatozoa with neck pathology in the ejaculate than the reference drug Prostatilen.

Analysis of the screening examination data showed that the comparison groups in terms of the relative count of spermatozoa with pathological changes in tail were representative and had a normal intragroup character of the distribution of indicators. Evaluation of the intragroup dynamics of the percentage of cells with abnormal tail morphology during treatment did not reveal the effect of the studied preparations on this indicator. As a result of statistical processing of data from a clinical study, no data were obtained on the presence of intra- and intergroup differences in the relative count of spermatozoa with tail pathology in the ejaculate during treatment with the studied drugs (Figure 3d). Thus, in the course of the clinical study, it was shown that the preparations Prostatilen AC and Prostatilen did not have a significant effect on the maintenance of the spermatozoa population with tail pathology.

Discussion.

Impaired sperm motility is one of the main factors in male infertility. Cell motility depends on the secretory activity and condition of the prostate gland. Due to the fact that the prostate extract (the main active component of the studied drugs) has an organotrophic effect (reduces the degree of edema, leukocyte infiltration, normalizes the secretory function of prostate epithelial cells), one of the predicted effects of the studied drugs was considered their effect on the increase in the population of mobile spermatozoa, and in the registered drug Prostatilen AC due to the presence of arginine, glycine and zinc in its composition, this effect should be more pronounced.

One of the important indicators of the semen analysis is the assessment of the morphological structure of spermatozoa. With a decrease in the number (both absolute and relative) of normal spermatozoa, due to various disorders of spermatogenesis, natural fertilization becomes problematic. Defective spermatogenesis and some forms of epididymal pathology are often associated with an increased number of abnormal spermatozoa. Morphological defects are often combined. The abnormal spermatozoon usually has a reduced fertilizing potential, depending on the type of anomaly, and may also contain abnormal DNA. Morphological defects are associated with increased DNA fragmentation, increased risk of structural chromosomal aberrations, immature chromatin, and aneuploidy. That is why the main emphasis is placed on the shape of the sperm head, although the pathology of the flagellum (its middle and main parts) is also considered as an aspect of reduced fertility).

Zinc deficiency is one of the main etiological factors contributing to spermatogenesis disorders. This is confirmed by the fact that many reproductive and sexual disorders have been eliminated against the background of the additional appointment

of this microelement. The simplest and most objective method for assessing the morphology of spermatozoa is recommended by the WHO ("WHO guidelines for the examination and processing of human ejaculate" Fifth edition 2010). According to this document, all spermatozoa are first of all graded as "normal / abnormal", and the latter, in turn, are divided according to the main location of the defect (pathology of the head, acrosome, neck, flagellum (tail)). The reference value of the relative count of normal spermatozoa in the ejaculate, according to WHO guidelines, should be at least 50% [15].

The acrosome is located in the head of the spermatozoon, in front of the nucleus under the plasma membrane and plays an extremely important role in the process of fertilization. The acrosome is formed during spermatogenesis and can be considered as a modified lysosome. Acrosomal reaction - exocytosis of the contents of the acrosome for local destruction of the zona pellucida and overcoming this barrier by the spermatozoon (during the acrosomal reaction, the outer membrane of the acrosome and the cell membrane merge. In this case, hyaluronidases, proteases (including acrosin), glycosidases, lipases, neuraminidase, and phosphatases, which cleave molecules of the zona pellucida to overcome this biological barrier by the spermatozoon) [15]. Pathological changes in the acrosome were assessed based on WHO guidelines (the head should be smooth with a clear contour, oval. It should have a clearly defined acrosomal region occupying 40–70% of the head area. The acrosome should not contain large vacuoles and no more than two small vacuoles that should not occupy more than 20% of the head. The post acrosomal region should not contain any vacuoles) but without specifying the type of violation [15]. The results of the study were recorded as the total relative number of spermatozoa with acrosome pathology, which does not contradict the requirements of the above guidelines.

The pathology of the spermatozoa neck was carried out taking into account the WHO recommendations using the appropriate equipment, methodological and reagent base (the neck should be thin, clearly defined and approximately the same length as the head. The main axis of the neck should coincide with the central axis of the spermatozoon head. The cytoplasmic drop is examined as abnormal only if it is excessively large, that is, when it exceeds one-third the size of the sperm head. Neck and midsection defects: asymmetrical attachment of the midsection to the head (heteroaxiality), thick or irregularly contoured, excessively curved, abnormally thin or any combination of the above characteristics).

Pathological changes in the tail (flagellum) of the spermatozoon can be varied (defects in the main part of the flagellum: short, multiple, broken, hairpin, with a pronounced angle, width with an irregular contour, twisted, or any combination of these characteristics). However, in this study, the specific nature of violations of the morphology of cell organelles was not significant, since first of all, the task was to assess the effect of the studied drugs on spermatogenesis in general, according to generally accepted indicators of ejaculate. In this regard, all types of pathological changes in the tail were recorded as part of the isolation of one population of cells with a defect in this structure.

Actually, there are no clinical guidelines for male patients seeking fertility treatment. Meanwhile identifying the dietary factors that can influence male fertility potential is of high importance [16]. Several studies focus on antioxidant supplementation therapy [17,18]. No guideline exists for the antioxidant dose regimen and treatment duration as well.

The pharmacological activity of ZAG was revealed in the experimental models of oligo-, astheno- and teratozoospermia, which were characterized by statistically significant differences compared with the control groups [10].

The addition of the regulatory peptides of the prostate to this composition made it possible to develop Prostatilen AC medicine, which effectiveness has already been proven by real clinical practice studies in management of patients with chronic prostatitis and impaired fertility [11-14]. Zhukov et al. [13] demonstrated that the additional effect of ZAG increases the number of spermatozoa forms with progressive motility and their morphologically normal forms in semen analysis. In other study the treatment with Prostatilen AC for 20 days in patients with infertility more effectively improved semen parameters: progressive sperm motility, normal morphology compared to the group treated with Arginine-zinc complex [14]. At 5 days after the end of therapy, the proportion of spermatozoa forms with progressive motility increased by 62% compared to the baseline in the group of patients with chronic abacterial prostatitis who received Prostatilen AC ($p < 0.001$) and only by 10% in the control group [14].

In our study the addition of ZAG to the regulatory peptides of the prostate composition in Prostatilen AC also resulted in significantly increased count of spermatozoa with a fast progressive motility (after therapy $p = 0.0004$) and of normal forms of spermatozoa (after therapy $p = 0.0118$) as well as in significantly decreased abnormal spermatozoa count with head, acrosome or neck pathology in the ejaculate compared to the reference drug.

Conclusion.

Prostatilen AC, rectal suppositories compared to the drug Prostatilen rectal suppositories, 3 mg, had a statistically significant and clinically significantly superior efficacy in relation to initially impaired sperm parameters (improve of sperm motility, restoration of morphologically normal sperm, decrease in forms of abnormal spermatozoa with head, acrosome or neck pathology). This drug could be recommended to use in the treatment of patients in whom chronic prostatitis occurs with concomitant disorders of sexual and reproductive functions.

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ВЛИЯНИЕ ДОБАВЛЕНИЯ АРГИНИЛ-ГЛИЦИНАТА ЦИНКА НА ПОВЫШЕНИЕ ЭФФЕКТИВНОСТИ БИОРЕГУЛЯТОРНЫХ ПЕПТИДОВ ПРЕДСТАТЕЛЬНОЙ ЖЕЛЕЗЫ ПРИ ЛЕЧЕНИИ ПАЦИЕНТОВ С НАРУШЕННЫМИ ПАРАМЕТРАМИ СПЕРМЫ.

Рыбалов М.А.¹, Боровец С.Ю.¹, Петленко С.В.², Краснов А.А.³, Апрятина В.А.⁴.

¹НИЦ урологии, НИИ хирургии и неотложной медицины, ПСПбГМУ им. И.П. Павлова,

²ФГБУН Институт токсикологии ФМБА России,

³Российский Государственный Педагогический Университет им. А.И. Герцена, Министерство науки и высшего образования Российской Федерации,

⁴Институт трансляционной биомедицины, Санкт-Петербургский государственный университет, Санкт-Петербург, Российская Федерация.

Резюме.

Препарат Простатилен®АЦ суппозитории ректальные был разработан на основе ранее зарегистрированного препарата, содержащего биорегуляторные пептиды простаты - Простатилен® суппозитории ректальные, 3 мг, и отличается введением в композицию активной фармацевтической субстанции цинка аргинил-глицината дигидрохлорид (ЦАГ). Целью исследования было оценить позитивный эффект добавления ЦАГ в состав препарата при лечении пациентов с нарушением сперматогенеза.

Обследовано 98 мужчин в возрасте 25-45 лет (в среднем 35,2±4,3 года) с верифицированным диагнозом хронического абактериального простатита и сопутствующими нарушениями репродуктивной функции в рандомизированном, мультисетовом, открытом клиническом исследовании III фазы. Продолжительность участия пациентов в исследовании составила 14-16 дней, период скрининга - 2-3 дня, продолжительность терапии - 10 дней, итоговое обследование - 2-3 дня. Основная группа (n=49) получала терапию Простатилен АЦ 1 раз в сутки,

контрольная группа (n=49) получала Простатилен 1 раз в сутки. Всем пациентам был проведен стандартный анализ спермограммы до и после лечения. Проводили анализ полученных данных.

В ходе анализа среднестатистических данных в группах сравнения было установлено, что исследуемый препарат Простатилен АЦ суппозитории ректальные приводит к увеличению общей популяции подвижных сперматозоидов (клетки А+В+С) на 14,3%, а препарат сравнения Простатилен суппозитории ректальные, 3 мг способствует повышению данного показателя на 4,1% по сравнению с результатами скринингового обследования с высокой эффективностью в отношении повышения относительного содержания сперматозоидов с быстрым поступательным движением (по окончании терапии Простатилен/Простатилен АЦ $p=0,0004$). Простатилен АЦ статистически значимо повышал содержание в эякуляте нормальных форм сперматозоидов, проявляя достоверно более высокую эффективность, чем Простатилен® ($p=0,0118$). У пациентов, получивших препарат Простатилен АЦ количество патологически измененных форм сперматозоидов уменьшилось на 12,4% (по окончании терапии - 55,57%), а в группе сравнения (Простатилен) на 6,5% (по окончании терапии - 58,90%) со статистически значимым уменьшением относительного содержания сперматозоидов с патологией головки, акросомы и шейки по сравнению с контрольной группой.

Простатилен АЦ по сравнению с препаратом Простатилен обладал статистически достоверно и клинически значимо превосходящей эффективностью в отношении исходно нарушенных показателей спермограммы (повышение содержания сперматозоидов с быстрым поступательным движением, восстановление популяции нормальных сперматозоидов, уменьшение относительного содержания сперматозоидов с патологией головки, акросомы и шейки). Данное лекарственное средство целесообразно использовать в терапии пациентов, у которых хронический простатит протекает с сопутствующими нарушениями половой и репродуктивной функций.

Ключевые слова: нарушение сперматогенеза, цинка аргинил-глицинат, биорегуляторные пептиды простаты, хронический простатит.