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Assessment of efficiency and the safety of Ovariamin® drug in normalization of menstrual cycle

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ABSTRACT

We performed an open controlled trial of efficiency and the safety of Ovariamin® drug in treatment of menstrual disorders. The research included 33 patients with menstrual disorder which were divided into 2 groups: the 1st group — menstrual disorders /ICD-10/N91. The absent scanty and infrequent menstruation (n = 17); the 2nd group — menstrual disorders / ICD-10/ N92. Abundant, frequent and irregular menstruations (n = 16). The analysis of clinical efficiency of administration of Ovariamin® drug in 3 months showed the following: normalization of menstrual cycle in the 1st group was registered in 52.9% of patients, in the 2nd group — in 62.5%; decrease of menstrual pain was registered in 52.9% in the 1st group and in 62.5% in the 2nd group. Satisfaction of patients in the end of the therapy was revealed in 88.2% in the 1st group, and in 93.8% in the 2nd group respectively; efficiency in maintenance of regular menstrual cycle in the next 6 months after treatment was revealed in 76.5% of patients of the 1st group, and in 75% of the 2nd group of patients.

Introduction

The concept of life quality is based on a multicomponent comprehension of health according to definition of the WHO according to which life quality changes at change of health. Earlier conducted researches showed that life quality of women depends largely on menstrual cycle therefore health maintenance and restoration of reproductive health of women is one of the most important problems of modern gynecology. Menstrual disorder is one of the most frequent reasons for women to visit an obstetrician-gynecologist. According to different authors to any extent menstrual disorder is registered at 20–35% of patients, besides, more than 60% of healthy women during life have these or those implications of such disorder. Menstrual disorders are characterized by change of recurrence, duration and volume of menstrual blood. The menstrual cycle (MC) averages 28 days, in the normal condition — from 21 to 35 days. Menstruation duration is 3–7 days (on the average 4–5 days), blood loss — from 50 to 150 ml (on the average 70–100 ml). Menstrual disorders can be both in the presence of ovulation, and at its absence.

Definitely influence of environmental factors, alcohol abuse, smoking, alimentary addictions, sedentary lifestyle can break appropriate work of female gonads that leads to clinical implications in the form of menstrual disorders. Also abnormal labors, abortions, inflammatory diseases in which sensitivity of the receptor apparatus of ovaries, uterus to normal gonadotrophic stimulation is damaged can

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be the reasons of menstrual disorders. Consequences of changes of subthalamic regulation of gonadotrophic function of hypophysis can be a trigger. The rhythm of egestion of follicle-stimulating and luteinizing hormones or their normal ratio necessary for ovulation is damaged. The mechanism of emergence of anovulatory cycles is more often connected with regulation disorder on the part of "hypothalamus — hypophysis — ovaries" system when there is no additional emission of luteinizing hormone by pituitary structures in the middle of menstrual disorders [1–3].

There is sufficient amount of therapeutic methods of impact on female reproductive health, however quite often arising resistance to standard schemes, low tolerance to hormonal drugs, unwillingness of the woman to use them or existence of contraindications determine looking for new options of treatment.

Ovariamin® is the natural bioregulator of Cytamines class that supports physiological function of ovaries and who is "adapting" the woman's organism on impregnation. Ovariamin® is the result of long-term collaboration of the "Longvi-Farm" company and leading Russian scientists of S.M. Kirov of Military Medical Academy (St. Petersburg) and St. Petersburg Institute of Bioregulation and Gerontology of North West Branch Russian Academy of Medical Sciences.

The product belongs to a new class of the agents created on the basis of the theory of a peptide bioregulation — Cytamines. Cytamines are not drugs and influence precisely on organs and tissues from which they are received. They help to optimize address good nutrition and function of organs. Cytamines don't contain preservatives and are compatible to other medicines. Ovariamin® supports function of ovaries at the natural level and is applied in the following cases:

• functional failure of ovaries (including when planning conception; is applied before pregnancy);

• adjustment of menstrual cycle;

• ovarian failure;

• pre-surgical and postsurgical period at gynecologic operations or abortion;

• disturbances of functions of the ovaries connected with hormonal disorders;

• unwillingness to take hormonal therapies or contraindication to them.

At the cellular level influence of negative factors of the external environment is presented in disturbance of separate cellular communications and failure of processes of cell neogenesis. It is required to level these influences for maintenance of functions of ovaries. Cytamines solve this problem by means of peptides, the substances regulating intracellular processes and ensuring normal functioning ofthe organs and tissues. They represent albuminous compound from a set of amino acids. All peptides have "specialization", i.e. they focally influence a concrete organ, for example, heart requires influence of cardiac peptides, for a liver — liver peptides etc. Peptides congenerous to organ are used for maintenance of function of ovaries during creation of the Ovariamin® drug. These peptides are received from ovaries of animal origin and are all-natural in structure. Thus, the product makes selective impact on cells of ovaries of the woman. Congenerous peptides of Ovariamin® drug participate in maintenance of function of ovaries at the cellular level, normalizing internal processes of neogenesis in each cell. The Ovariamin® bioregulator exerts impact both on weakened, and on healthy cells. In case in a cell there are compromised bonds, then the regulatory peptide "restores" a chain. If "gaps" aren't revealed in a cellular chain, then peptides of Ovariamin® drug serve as "nutritious" substance, "fuel" for a healthy cell. The conducted researches prove that treatment with Ovariamin® drug regulates a cellular metabolism of ovaries, supports process of formation and maturation of follicles, and also participates in correction of menstrual and genesial functions. Adequate correction of hormonal attrition of ovaries represents a difficult clinical task and demands an integrated approach that dictates the necessity of development of new and more effective methods of treatment [1, 2, 4, 5].

Aim of the Research

Studying of possibility of Ovariamin® drug usage in treatment of patients with menstrual disorders.

Materials and Methods

The open controlled trial of efficiency and the safety of Ovariamin® drug in treatment of menstrual disorders is conducted from October, 2016 to February, 2017. Regular menstrual cycle was defined as menstrual cycle lasting from 21 up to 35 days.

In the furtherance of this aim the following things were required: to study changes in duration of menstrual cycle at the end of therapy and in 6 months after treatment; to estimate changes in intensity of menstrual pains and satisfaction of patients and clinical performance in the end of the therapy.

The trial included 33 women with menstrual disorder who were divided into 2 groups: the 1st group was with menstrual disorders /ICD-10/ N91. The absent scanty and infrequent menstruation (n = 17); 2nd group was with menstrual disorders /ICD-10/ N92. Abundant, frequent and irregular menstruations (n = 16).

Ovariamin® was prescribed according to local product instruction within daily clinical practice of the attending physician: from the 5th to the 14th day of menstrual cycle in a dose of 3 pills 3 times a day in 15 min before meals during 3 menstrual cycles.

Criteria of including into trial were: age of 17–34 years, irregular menstrual cycle, Patient Informed Consent.

Criteria of an exception: malignant tumors of any localization, reception of the combined oral contraceptives (COC), pregnancy, existence of acute diseases or exacerbation of chronic diseases, vaginal bleedings of obscure etiology.

All patients were examined in Medical Consultation Centre functioning based on the Novosibirsk State Medical University. All patients were performed the standard gynecologic examination including bimanual vaginal examination, US of small pelvic organs (assessment of ovarian reserve, the number of antral follicles) and definition of AMH (Anti-Mullerian Hormone) before treatment and in 6 months after initiation of therapy.

The undesirable phenomena (their characteristics and frequency) which were classified by a 4-point categorial scale were considered for an assessment of the safety and acceptability of therapy:

• excellent safety and acceptability (no side effects);

• good safety and acceptability (mild side effects that aren't demanding a medical intervention);

• satisfactory safety and acceptability (moderate side effects; drugs order for their elimination);

• bad safety and acceptability (expressed side effects demanding drug withdrawal).

The next visits were planned for performing treatment according to routine schemes of medical researchers:

The visit 1 included screening at the beginning of the research.

The visit 2 was conducted after 3-month management of patients from an initiation of treatment.

The visit 3 was conducted after 6-month management of patients from an initiation of treatment.

Communication was carried out via phone, e-mail, WhatsApp any day of a research for tracking of the serious or spontaneous undesirable phenomena.

The research is performed according to the principles of the Declaration of Helsinki of the World Medical Association "Ethical Principles for Medical Research Involving Human Subjects" and Rules of clinical practice in the Russian Federation approved by the Order of the Russian Ministry of Health of 19.06.2003 No. 266 [6]. Patients signed Patient Informed Consents.

The statistical analysis was carried out with Statistica 6 software package, Microsoft Excel program. Statistical reliability was estimated on nonparametric (Wilcoxon — Mann — Whitney U-test) criterion.

Results and Discussion

All patients of the age of 12–14 years have had menarche in the anamnesis; menstrual cycle was established within 1.5–2 years in 17 patients (100%) of the 1st group and in 16 patients (100%) of the 2nd group; abundant and painful menstruations were registered in 11 women (64.7%) of the 1st group and in 10 women (62.5%) the 2nd group. Pregnancies were in 11 women (64.7%) of the 1st group and in 12 women (75%) the 2nd group, among them labors — in 6 women (35.3%) of the 1st group and in 10 women (62.5%) the 2nd group; abortions in 5 women (29.4%) of the 1st group and in 10 women (62.5%) the 2nd group; 7 women (41.2%) of the 1st group and 7 women (43.8%) the 2nd group have had abortions.

Normalization of menstrual cycle was registered in 9 patients (52.9%) of the 1st group and in 10 patients (62.5%) of the 2nd group after a 3-month course of administration of Ovariamin® drug; decrease of morbidity of menstruations was revealed in 9 patients (52.9%) of the 1st group and in 10 patients (62.5%) of the 2nd group; decrease of irritability, tearfulness — in 15 patients (88.2%) of the 1st group and in 14 patients (87.5%) the 2nd group. In general the effect of administration of Ovariamin® were estimated as positive in 15 patients (88.2%) of the 1st group and in 15 (93.8%) the 2nd group; 2 (11.8%) patients of the 1st group and 1 patient (6.25%) of the 2nd group didn't notice any effect of therapy. Collateral reactions or intensifying of complaints against the background of drug administration of weren't registered. As the analysis has showed, Ovariamin® was effective in achievement and maintenance of regular menstrual cycle in 13 (76.5%) patients of the 1st group and in 12 (75%) of the 2nd group.

Calculation of antral follicles was carried out for the purpose of definition of ovarian reserve at ultrasonography. The following things were revealed: the averaged number was 7 in the 1st group, in the 2nd group — 14, in 6 months from an initiation of treatment the number of antral follicles in the 1st group was 8, in the 2nd group — 12. Thus, the quantity of antral follicles in 6 months from initiation of treatment with Ovariamin® drug did not change.

The average level of AMH in blood serum in patients of the 1st group prior to treatment was 3.02 ± 0.3 ng/ml, and AMH was higher 8.4 ± 0.1 ng/ml in patients of the 2nd group. Significant changes were not observed in 6 months from initiation of treatment: the average level of AMH in blood serum in patients of the 1st group was 3.34 ± 0.2 ng/ml, in patients of the 2nd group AMH was 8.1 ± 0.3 ng/ml. Pregnancy was considered as the desirable phenomenon, the result of pregnancy was fixed. Only 4 patients became pregnant: 1 patient (5.9%) in the 1st group and 3 patients (18.8%) in the 2nd group.

The conducted research showed favorable effects of non-medicinal product Ovariamin® on normalization of vegetative function, rhythm of menstruations, folliculogenesis, growth of endometrium [4]. In the end of treatment the average duration of menstrual cycle was 29 days in patients of the 1st group and 28 days in patients of the 2nd group.

Conclusion

Ovariamin® showed effective restoration of regular menstruation at therapy of menstrual disorders. Treatment with Ovariamin® drug is associated with high satisfaction on the parts of patients and doctors. Ovariamin® allows normalizing menstrual disorder softly and delicately, granting the absence of serious endocrinologic or gynecologic pathology.

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