University Clinical Center of the Republic of Srpska Banja Luka
Clinic for Internal Medicine - Department of Endocrinology
Phone Number: +387 51 342 563

Research title: "The effect of metformin and myoinositol on metabolic outcomes in women with polycystic ovary syndrome: role of body mass and adiponectin in a randomized controlled trial"

Examiner (researcher): Valentina Soldat-Stanković MD MSc.

Notice for potential respondents in the clinical research entitled: "The effect of metformin and myoinositol on metabolic outcomes in women with polycystic ovary syndrome: role of body mass and adiponectin in a randomized controlled trial

This document describes a clinical research for patients who choose to participate in the study. The trial was reviewed and approved by the "Ethics Committee of the University Clinical Center of the Republic of Srpska Banja Luka". It is up to you to decide if you want to take part in the study. If you choose to join the study, you must sign the pages at the end of this form to show that you agree to participate.

You should make your decision after the examiner (researcher) has explained this trial to you and after you are familiar with the purpose of the trial and the possible risks.

You can change your mind at any time and request that, even if you sign your consent, your data would not be used for the mentioned research.

If you have any questions about your rights while participating in this research, call the Ethical Committee of the University Clinical Center of the Republic of Srpska Banja Luka on the following phone No.: +387 51 342-176 or personally to the researcher's phone No.: +387 65 617 019 (Valentina Soldat-Stanković MD MSc.).

The aim of this research was to compare the hormonal and metabolic profile between the groups of women with PCOS and women of the control group and to determine the effect of metformin and myoinositol therapy in the group of patients with PCOS on the hormonal and metabolic profile of patients with polycystic ovary syndrome.

Participation in this clinical research includes consent for taking medical history, performing a physical examination, measuring body weight and height, waist circumference and hirsutism score and estimation of body composition by using bioelectrical impedance

analysis, transvaginal ultrasound examinations. and taking blood samples after 12 hours of fasting during the early follicular phase for hormonal assessment, insulin and glucose during 120 min OGTT test, adiponectin, lipid profile and high sensitive CRP, after which two groups would be formed: study and control group. If you are diagnosed with polycystic ovary syndrome according to the Rotterdam criteria, you will be assigned to a study group and randomly selected for one of the two treatment regimens in a 1:1 ratio, the metformin treatment regimen and the myonositol treatment regimen. If you are prescribed metformin therapy, you will take the medicine for 6 months at a dose of 1500 mg, with an introductory dose of 1000 mg during the first two weeks of treatment. Gastrointestinal disturbances may occur during metformin therapy. If you are selected for the myoinositol treatment regimen, you will take myoinositol 2 g plus 200 mg folic acid every day for six months. The applied therapy has so far shown no side effects.

Monitoring will be performed at quarterly and six-month intervals through a follow-up examination. At the end of the six-month treatment, your body height and weight, waist circumference will be measured, you will undergo a complete physical examination, hirsutusm score evluation and body composition analyses. Blood samples will be taken for laboratory tests of insulin and glucose during 120 min OGTT test, adiponectin, lipid profile and high sensitive CRP.

If you choose to participate in the research, you allow us to use the data for the purpose of establishing new scientific knowledge and producing scientific publications arising from it. This permission shall remain valid after the end of the trial. Your personal and health information **will be kept confidential**. You can request access to your personal information (such as name and address) at any time and correct it as necessary.

Your health data will be combined with data on other people in the trial. These data from the study will provide a more detailed insight into the effects of myoinositol on the hormonal and metabolic profile of patients with PCOS compared with metformin therapy, all with the aim of improving further treatment. All data is confidential.

By signing the consent, you agree to provide your personal and health information for use in the manner described in this document. The researcher can publish the research results in relevant scientific publications in accordance with the applicable regulations as well as use them to plan new trials. Your name will not appear in any of these reports.

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Consent form for respondents in the clinical research entitled "The effect of metformin and myoinositol on metabolic outcomes in women with polycystic ovary syndrome: role of body mass and adiponectin in a randomized controlled trial
I declare that I am familiar with all aspects of participation in the clinical research entitled "The effect of metformin and myoinositol on metabolic outcomes in women with polycystic ovary syndrome: role of body mass and adiponectin in a randomized controlled trial" which will be conducted at the Clinic for Internal Medicine at the Department of Endocrinology at the University Clinical Center of the Republic of Srpska Banja Luka with the aim of gaining new knowledge about the interconnectedness of insulin sensitizer therapy to improve the metabolic and hormonal profile in women with polycystic ovary syndrome. I am aware of the fact that I/the person for whom I give written consent as part of this research, will give my medical history, undergo a physical examination, measurement body weight and height, waist circumference and hirsutism score and estimation of body composition by using bioelectrical impedance analysis, transvaginal ultrasound examinations. and give blood samples after 12 hours of fasting during the early follicular phase for hormonal assessment, insulin and glucose during 120 min OGTT test, adiponectin, lipid profile and high sensitive CRP. As part of my participation in this research, I am aware that if I meet the diagnostic criteria, I will undergo one of the therapeutic treatments for polycystic ovary syndrome for six months. The results of testing during outpatient examinations or hospitalization of patients in the Clinic for Internal Medicine at the Department of Endocrinology will be used as part of the participation in this research.
I am also aware of the fact that the above-mentioned actions do not differ in any way from those in routine treatment and therapeutic procedures used in the treatment of patients with polycystic ovary syndrome.
I confirm that my participation in this research is voluntary. All data obtained by this study are confidential and will be used exclusively for the purpose of scientific publication. This data will not be used for profit. The material will not be used for the purpose of genetic

manipulation. The identity of the person giving out data will not be disclosed in any of the published reports. As a respondent or his/her representative, I may refuse to participate or withdraw from this research, as well as prohibit the use of data at any time without consequences in terms of health care. I was allowed to ask questions and I received a satisfactory answer to each question asked. The values of these findings and their clinical and other significance will be presented to me if I show interest in them. I know that giving data for this study is my own choice. I certify that I have received a copy of this form as well as that I have read it.

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This form is personally explained and provided by: _____, on _____, in Banja Luka.

Name of research participant or his/her representative

_____ Date: _____

Signature of research participant or his/her representative

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