Effect of Semaglutide on the Psoriatic Lesion in Patients With Type 2 Diabetes Mellitus

Date : 03.may 2023.

Information and informed consent for patients with psoriasis and type II diabetes mellitus treated with semaglutide

Please read carefully all the Information, as well as the Informed Consent for voluntary participation in the research (hereinafter: Informed Consent). If you do not understand any part of the Information and the Informed Consent, please contact your doctor/researchers. Your participation in the research is voluntary and you can withdraw at any time, without any consequences on your treatment/quality of life. If you decide to participate in this research, you and the researcher will be asked to sign the Informed Consent, with an indication of the date, whereby you will receive one copy of the consent, while the other will be withheld by the researcher.

We hereby invite you to participate as a subject in the scientific research entitled "Effect of semaglutide on the inflammatory response and clinical course of psoriatic lesions in patients with type II diabetes mellitus" in which the effect of the drug semaglutide on the severity of the disease in psoriatic patients with type two diabetes mellitus will be examined. We want you to participate in the mentioned research, since a blood (serum) sample will be taken from you in order to determine the effect of the mentioned drug on the severity of the disease.

The research will be conducted at the Skin and Venereal Diseases Clinic of the University Clinical Center of the Republika Srpska in Banja Luka. The examination is conducted for the purpose of preparing the doctoral dissertation of **Dr. Jelena Petković-Dabić (researcher)**.

1. Objectives and duration of the research

The research objective is to determine whether there is a correlation between the severity and prognosis of the disease, in the examined patients with psoriasis and diabetes mellitus type II, who received the drug semaglutide, compared to another group of patients who did not receive semaglutide during the research.

During the research, which is planned to last three months for each patient, it is necessary that you come to the research center - Skin and Venereal Diseases Clinic of the University Clinical Center in Banja Luka, a total of two study visits.

On the first day of research - First visit and on the last day - Second visit, after three months.

The duration of an individual visit will not be longer than 2 hours.

The envisaged research will be carried out as part of the doctoral dissertation. All submitted samples will be used for scientific tests.

Characteristics of the subjects

You are invited to participate in this research because you have psoriasis and diabetes and are being treated with standard therapy and semaglutide.

30 patients will be included in the research itself, two groups of 15 subjects each.

- One group that will consist of patients suffering from psoriasis and type 2 diabetes mellitus, who will receive the drug semaglutide according to the established medical instructions for the drug for the treatment of diabetes with this drug, which will be prescribed by an endocrinologist and which the patient will receive by prescription, at no additional cost. You give yourself the medicine, after education at the Department of Endocrinology, and that by injecting it under the skin once a week. The initial dose of the medicine is 0.25 mg once a week, for the duration of 4 weeks. Then the dose is increased to 0.5 mg per week, for the duration of 4 weeks. After at least 4 weeks, the dose can be increased from 0.5 mg to 1 mg per week. Described side effects of the drug are nausea, vomiting, redness and swelling at the localization of drug application.

- The second group, patients suffering from psoriasis and type 2 diabetes mellitus, who are already on therapy with any other drug from the group of oral antidiabetics.

Patients from both groups of subjects will be allowed to use local therapy for the treatment of psoriasis, in the form of emollient creams (cream for dry skin care), during the entire research period. It is necessary that you agree with our instructions on which drugs you may and may not take during the 3 months of the research.

The age of the subjects is from 18-65 years and subjects of both sexes will be included. The research will be carried out for 3 months and through a total of 2 visits of the subjects to the research center (Skin and Venereal Diseases Clinic of UKC RS). The serum sample will be taken twice during two visits, namely: on the first day of the research and on the last day of the research.

2. Description of the procedures to which the subject will be exposed during participation in the research

A) Taking a blood sample

The procedures that are planned to be performed on the subjects during the first and second visit include taking a blood sample from a fasting vein - a total of 2 test tubes (standard, regular

procedures for laboratory tests) and do not differ from the procedures that would be applied if the patient was not included in the research.

B) Clinical examination

In addition to the procedure of taking a blood sample from a vein in the morning on an empty stomach (serum sampling), patients will also undergo an examination by a dermatovenerologist - a clinical assessment of the severity of psoriasis, which is determined through a clinical examination and determination of the severity of psoriasis and the spread of changes on the skin of the entire body. Apart from that, patients will receive a questionnaire that assesses the quality of life of patients suffering from psoriasis, which the patient must fill out during both visits. Completing the questionnaire of a total of 10 questions takes no longer than 5 minutes. The questions are composed so that the doctor, based on your answers, can assess how much the skin problem affected your life during the past 7 days.

(The questionnaire is attached to the Form)

3. Potential risks and discomforts related to the subjects' participation in the research

Taking a blood sample for research purposes does not imply exposing the patient to any additional procedures, nor does it in any way affect the further course and outcome of the patient's treatment.

The research does not involve any risk to the health of the subjects, except for the possible appearance of bruises or pain at the injection site, and possible mild dizziness, which is expected and normal, taking into account that the mentioned blood samples are very often taken as part of the regular procedure of treatment/care of the patient. **In this sense, there are absolutely no risks for the subject (development of allergic reactions, transmission of infection, etc.) that can be linked to the use of their samples for research purposes.**

The most frequently described side effects of the applied drug semaglutide are very mild, and can occur in the form of nausea, vomiting, and redness and swelling at the localization of drug application.

4. Potential benefit for the subject and/or society related to the subject's participation in the research

By including subjects/donors in the research, primarily an indirect benefit is achieved, both for the subject and for the entire social community, which is reflected in the development of biomedical sciences and disciplines, which further leads to the improvement of public health and individual health, since the obtained results can be used in correction therapy.

Scientific papers, as the crown of scientific research, bring new knowledge aimed at solving practical problems in medicine. Please note that the subjects will not benefit financially from the planned research.

5. Benefit for the researcher(s) related to the subject’s participation in the research

The results of the research will be used for the purpose of preparing a doctoral dissertation, publishing original scientific papers, and in order to achieve new knowledge in the field of dermatovenerology.

Clinic researchers will not receive financial benefit, and the benefit of research is reflected exclusively in the contribution to knowledge in the field of medicine.

6. Note on treating medical data confidentiality/privacy assurance

According to the Law on Protection of Personal Data of Bosnia and Herzegovina ("Official Gazette of BiH" number: 89/11, 76/11, 49/06), as well as the European Union General Data Protection Regulation (GDPR) EU2016 /679), researchers are responsible for compliance with legal norms when using personal data of subjects.

All subjects participating in the research are guaranteed privacy/medical data protection by all participants in the research: researchers employed at the Center, doctors and other medical staff employed at the University Clinical Center of Republika Srpska (hereinafter: UKC RS).

The protection of personal and medical data of subjects is guaranteed according to the principles of pseudo-anonymization, which include ensuring the privacy of patients, and the procedure is carried out in such a way that each sample of medical waste is assigned an appropriate code (a combination of numerical and letter codes) that does not bring the sample into direct connection with the patient, but may provide access to his/her medical data if necessary. In addition, the principle of pseudo-anonymization allows subjects to request the results of research on their samples, as well as to request the destruction of the sample for envisaged research.

The principle of pseudo-anonymization includes the role of the responsible person of UKC RS and the responsible person of the Center. The responsible person of UKC RS is responsible for taking, properly storing, keeping records and handing over samples of medical material, as well as providing medical data to the researcher. The responsible person of the Center is in charge of receiving, coding and properly storing the sample of medical material.

7. Access to research data

By means of the researcher, you have the right to access the data collected about you and ask for their corrections if they are incorrect, during the implementation of the research or at the end of the research.

If you have any questions or complaints regarding the handling of your data, you can first contact the researchers, who will forward your request to the institution responsible for the protection of personal data. In addition, if you have a complaint regarding the treating of personal data confidentiality and the method of ensuring your privacy, you can send it directly to the competent authority responsible for the implementation of the Law on Protection of Personal Data (Personal Data Protection Agency in Bosnia and Herzegovina).

8. Authority that approved the research

Ethics committee for research on humans and biological material of the Faculty of Medicine, University of Banja Luka.

Ethics Committee of the University Clinical Center in Banja Luka.

9. Name and surname, contact information of the researcher for additional questions/issues during the research

Dr. Jelena Petković-Dabić

(e.mail: jelena.petkovic81@yahoo.com; phone number: 065 671 202)

Date:

Name and surname of the subject

_____

CONSENT TO PARTICIPATE IN THE RESEARCH

I _____ (full name in block letters) have read and fully understood the presented information and give my voluntary consent to participate in the clinical research.

I received detailed explanations about the objective, benefits and risks of the research from the doctor who is responsible for this research. I was able to ask any question related to the research, and I understood the answers I received.

After serious consideration, I have decided that I will cooperate with my doctor and follow his/her instructions regarding this clinical research. I also commit to inform my doctor immediately if I experience any change in my health condition during the research.

I understood that I can withdraw from the research at any time without fear of suffering any consequences in further treatment.

I have read the above described and give my consent. I will keep one copy of this document.

Subject's signature: _____

Date: _____

I, as the researcher, confirm that the purpose and procedures of this research, and the risks associated with it, were fully explained to the patient and that I gave a copy of the Informed Consent, signed by the researcher and the subject, to the subject.

Researcher's signature: _____

Date: _____