Wroclaw, 1.02.2021

Assessment of Er:YAG (yttrium-aluminium-garnet) Laser-Assisted Surgical Treatment in Medication-Related Osteonecrosis of the Jaw (MRONJ): A Clinical Trial

INFORMATION ABOUT THE STUDY

Title of the study: Treatment regimens for osteonecrosis of the jaw after bisphosphonates. The effect of vitamin D and Erbium:Yag Laser on therapeutic effects.

Name and surname of the researcher: DDS Filip Michalak

Dear Madam/Madam/Madam, you have been asked to participate in a research project. Before giving your consent, please read this 'Information' and make sure you understand it. This document describes the purpose of the study, procedures, benefits and risks resulting from the study. The researcher will clarify any doubts if necessary.

If you decide to participate in the research project, you will be asked to sign the 'Informed Consent Form to participate in the study'. You may also withdraw from participation at any time without giving a reason and without any consequences.

I. Purpose of the study

You are taking part in a research project aimed at developing the most optimal and effective treatment regimen for osteonecrosis of the jaw MRONJ

II. Course of the study

You will undergo a clinical and radiological examination. A detailed interview and medical history and history of taking bisphosphonates will be collected. The level of vitamin D in the plasma will be tested before starting the treatment and, depending on the result, during the treatment and after. You will be qualified for surgical or non-surgical treatment depending on the stage of MRONJ (osteonecrosis of the jaw) and randomly assigned in the case of surgical treatment to one of two methods using conventional surgery or using an erbium:yag laser.

Follow-up visits will take place after 7 days, 3 and 6 months after the procedure.

III. Risks associated with participation in the study

The therapeutic methods used are completely safe and can only have a beneficial effect on the healing process after the procedure. Any side effects and complications may be associated only with the disruption of tissue continuity related to the extent of the procedure or anatomical conditions.

IV. Benefits of participating in the study

Development of the best treatment regimen for osteonecrosis of the jaws depending on the stage of advancement, as well as the influence of vitamin D and its level in plasma on bone healing and regeneration processes in patients with osteonecrosis of the jaws.

Patient signature