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Treatment of peri-implant mucositis with an Er:Yag laser or an ultrasound. A randomized comparative clinical trial.

Informed consent form

” Treatment of peri- implant mucositis with an ER:Yag laser or an ultrasound. A randomized comparative clinical trial”.

Information for the research subjects

We would like to ask you if you would like to participate in a research project. In this document you will receive information about the project and what it means to participate.

What kind of project is it and why do you want me to participate?

Replacing lost teeth with dental implants is becoming increasingly common. The success rate for implant treatment is considered high, but new scientific studies show that more than 70% of individuals who have received dental implants have inflammation around them after 10 years. Various disease states such as peri-implant mucositis (inflammation of the gums around the implants) and peri-implantitis (inflammation that also causes the breakdown of the jawbone around the implants) can develop around the implants. These diseases are caused by bacteria that adhere to the surface of the implant. The implants are screw-shaped and usually provided with raw surfaces to improve healing in the bone. In the event of an infection, the removal of the bacteria on the raw implant surface with the conventional instruments used in similar inflammations around teeth (tooth loss) becomes difficult. To prevent a loss of the bone that anchors the implant, it is important to find effective methods to treat peri-implant mucositis at an early stage. To use hand instruments and mechanically remove bacteria from an uneven and raw implant surface has proven to be difficult. New methods such as laser treatment or the use of ultrasound have shown favourable results in previous trials.

You are being asked to participate in this study because you have inflammation at one of your implants. The aim of the study is, to study the effect of laser treatment in comparison with ultrasound treatment in peri-implant mucositis over 6 months.

The research lead for the project is Kristianstad University.

How does the study work?

Participating in the study means that your implants are examined through a clinical examination as well as an X-ray examination. Various measurements such as bacterial coating, pocket depth and bleeding are made at your implants. Photographs and occasional x-rays of your implants will be taken. You will be treated and checked repeatedly according to a schedule. Examination, control and treatment will take place at month 0, month 1, month 3, month 6. At each visit, the time required will be approximately 0.5 - 1.5 hours. If you choose to participate in the study, it is very important that you attend the scheduled visits. The ambition is that the treatment should lead to resolution of the inflammation at your implants to prevent loss of bone around them. During treatment, your implants will be randomly allocated to either be treated with a hard tissue laser or an ultrasound. A full medical history will be taken. You will also be asked to fill in a questionnaire about your experience of the examination, the control and the treatment. All elements included in the study are free of charge.

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Possible consequences and risks of participating in the study

If you meet the requirements for participating in the study, you will have the inflammation at your implants treated after the examination. There are no known risks with either the examination or the treatment.

What happens to my data?

The project will collect clinical data about your implants and record this information about you. The data that will be collected is, among other things, the amount of bacterial coating, pocket depth and bleeding around your implants. You will be given a code so that you cannot be identified while we treat and control your infection around the implant. Research data will be registered with this code number as identification. Your answers and your results will be processed so that unauthorized persons cannot access them. The code list is kept locked in a safe to which only relevant personnel have access. Customary confidentiality applies to the information that is entered into your treatment record which is of value for your treatment.

Kristianstad University is responsible for your personal data. According to the EU's data protection regulation, you have the right to access the information about you handled in the study, free of charge, and if necessary to have any errors corrected. You can also request that information about you be deleted and that the processing of your personal data be restricted.

If you want to take part in the data, you should contact Viveca Wallin Bengtsson by email: viveca.wallin_bengtsson@hkr.se .

Data Protection Officer by email: maria.gustavsson @hkr.se

If you are dissatisfied with the way your personal data is processed, you have the right to lodge a complaint with the Data Inspectorate, which is the supervisory authority.

How do I get information about the results of the study?

At the time of the examination, you will be verbally informed about the results of the examination. You will also be verbally informed of any other findings and receive a recommendation on what to do about this. The study will be published in a scientific journal and in this way, you can share the results of the entire study.

Insurance and compensation

During the examination and the treatment, you are protected by the dental insurance.

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Participation is voluntary

Your participation is voluntary and you can choose to cancel at any time. If you choose not to participate or wish to cancel your participation, you do not need to state why, and it will not affect your future care or treatment.

If you wish to cancel your participation, please contact the person responsible for the study (see below).

Responsible for the study

Responsible for the study is Viveca Wallin Bengtsson Kristianstad University Department of Oral Health, 29188 Kristianstad. Mail: viveca.wallin_bengtsson@hkr.se . Telephone: 044-250 3881.

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Consent to participate in the study

I have received oral and written information about the study and have had the opportunity to ask questions. The written information is possible to keep.

☐ I agree to participate in the study " Treatment of peri- implant mucositis with an ER:Yag laser or an ultrasound. A randomized comparative clinical trial”.

☐ I agree that data about me will be processed in the manner described in the research subject information.

Place and date	Signature