Clinical Study: Clinical, biochemical and radiological follow-up examinations to ensure the success of oral implants

Patient information / consent

Study director:

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Name of the participant Participant no .:_____

Dear Madam, dear Sir,

The research project entitled "Clinical, biochemical and radiological follow-up examinations to ensure the success of oral implants" aims to record the frequency of occurrence of inflammation of the mucous membranes or inflammation around titanium dental implants. In addition, a possible inflammatory reaction to titanium materials should also be assessed using swab samples and blood samples.

The aim of this research project is to examine your body's reaction to titanium dental implants using a clinical examination, swabs on the mucous membrane and finally a blood sample. Your blood cells in the test tube are also associated with titanium metal platelets, so that we can improve the recommendations for use of titanium dental implants based on the information received from all study participants.

We have put together some information below so that you can make your decision for or against participating in this study to the best of your knowledge. Regardless of which you decide, you will always receive the correct medical care based on current knowledge. You can withdraw your consent to participate at any time - there is no disadvantage for you.

It should be noted that no strict insurance has been taken out.

Information on the initial medical situation

Titanium implants are considered to be well tolerated by the body. They are already used in large numbers, but sometimes there is an inflammatory reaction and it is suspected that very occasionally people who are hypersensitive to such materials could also react.

A so-called smear can be used to determine bacterial colonization from the oral cavity near the implant and to draw conclusions about the inflammatory substances. During the clinical examination, the condition of the mucous membrane can also be assessed and the position of the implant (with the question of loosening, bone cysts, signs of inflammation, etc.) can be assessed using a standard x-ray.

If blood leukocytes are isolated from a blood sample, they can be brought into contact with metal preparations in the test tube and indicate a readiness to react to these preparations. "DNA" components can also be isolated from the blood cells as genetic information. This can be used to

investigate whether there is an individual tendency towards increased production or effectiveness of inflammatory messenger substances.

As with a standard blood sample, a “bruise” can then appear or, theoretically, a circulatory reaction or nerve damage can occur.

Voluntariness of the research study

Participation in this research study is absolutely voluntary. If you refuse to participate or withdraw your consent during the research study, you will not suffer any disadvantages and your data and any available blood samples will be destroyed. With your consent, it is declared that you have been informed about the nature, meaning and scope of this research study in a form that you can understand and that you have had sufficient opportunity to ask questions.

If you have any further questions, please contact the doctor in charge of you or the study director

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Privacy

The regulations on medical confidentiality and data protection are observed. Personal data and findings about you are collected, stored and encrypted (pseudonymised, i.e. neither your name, your initials nor the exact date of birth appear in the encryption code).
If you revoke your consent, the pseudonymized data stored will continue to be used in an irreversibly anonymized form or will be destroyed.

If the study results are published, the confidentiality of personal data is also guaranteed.

How does participating in the study look specifically for you?

In addition to the clinical examination, the smears to be performed and a possible standard X-ray, we also ask for a blood sample. This blood sample is "encrypted" (i.e. "pseudonymized") and sent to the allergy working group headed by Prof. Thomas (at the University Dermatology Clinic of the Ludwig Maximilians University in Munich). On the one hand, the cells isolated from it are brought into contact with titanium material in the test tube to see whether inflammatory substances or tolerance factors are released. On the other hand, DNA building blocks are isolated from the blood cells, which are used to examine whether there is a particular tendency towards the formation of certain inflammatory messengers. With my signature I also declare my consent for this blood donation, i.e. with a study-related blood sample of approx. 80 ml.

Are there any impairments for you if you participate in this study?

The smear examination, clinical examination and X-ray examination are carried out in the same way as standard procedures in the medical-dental examination.
The study-related venipuncture for blood collection is carried out according to the usual routine procedure for an arm vein. As with a standard blood sample, a “bruise” can then appear or, theoretically, a circulatory reaction or nerve damage can occur.

Benefit / risk

You have the advantage that during the follow-up examination of your dental titanium implants, there is an examination of inflammatory substances and readiness to react to titanium materials that goes beyond the scope of the standard examination. The benefit is, on the one hand, that by participating in this project you are helping to develop even better tolerability conditions for titanium implants. And on the other hand, the examining dentists offer you free teeth cleaning as a concession for participating in the examination. As described above, the risk of taking blood samples is the same as a standard blood sample in a doctor's office.

Consent to data verification / medical confidentiality

I agree that the disease data determined as part of the investigation study will be recorded and evaluated. The personal data will be encrypted using numeric coding. The principles of data protection are observed when handling the data. Only the examiners and authorized persons of the health authorities have access to the confidential data in which you are named within the framework of the relevant legal regulations. These persons are subject to confidentiality and are obliged to observe data protection. The data will only be decrypted if there is medical / scientific justification. The data is saved on a separate computer with password protection. If the consent is withdrawn, an irreversible anonymization takes place (or the data is deleted). You will not be named in any publication of the data for this clinical trial.

I consent to the collection and use of my personal data as part of the study.

_____ _____
Place, date (signature of the participant)

I hereby agree to participate in the study.

_____ _____ _____
Place, date (signature of participant) (signature of attending doctor)