03/22/2020

Informed Consent Form

YUZUNCU YIL UNIVERSITY DURSUN ODABAŞ MEDICAL CENTER INFORMED CONSENT FORM FOR RESEARCH

Informed Consent form for patient.

Dear patient,

Please read this document carefully and listen carefully to what we say. Detailed information about the research; Detailed information about your rights, benefits and risks of the research is included in this document. The purpose of these statements is to inform you about your health. Please indicate what you do not understand and your questions will be explained in detail. After agreeing to participate in the research, you can leave the research at any stage of the research if you think your questions have not been adequately explained or for any other reason. During the research period, any health problems arising from our research will be treated immediately in our hospital. You will not be charged any additional fee for participating in this research and you will not be paid any money. Thank you for participating in our research.

Name of the research: Peri-implant Phenotype, Calprotectin and Mmp-8 Levels in Cases Diagnosed With Peri-implant Disease

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Nazlı Zeynep ALPASLAN, working for the Van YYU . We are doing research examining the effect of the phenotype of peri-implant mucosa on the severity of peri-implant diseases and non-surgical mechanical treatment.

You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study

doctor or the staff.)

Subject of the research, purpose, method to be used, duration and process:
Our research aims to investigate to what extent the insufficiency of the soft tissue thickness around the implant, which is one of the reasons for this situation, affects the disease in individuals with infection and inflammatory conditions in the bone or gum tissue around the implant and whether this situation affects the treatment. Intraoral photographs will be taken along with clinical and radiological examination. Since infection and inflammation around the implant are associated with some biomarkers, a fluid sample will be collected from around the implant with paper strips and sent to the laboratory for analysis. The health of the soft tissue around the implant will be examined with routinely used plastic hand instruments. During soft tissue thickness measurement methods around the implant, the soft tissue will be anesthetized with spray. If any pain is felt, the area will be anesthetized locally. While anesthesia is present, the area around the implant will be cleaned mechanically with hand tools made of titanium that do not damage the implant, and the area will be washed with a salinelike solution (physiological saline). Then 1st, 3rd. You will be expected to come for a check-up in the 6th month and all clinical measurements will be repeated in the 6th month.

Type of Research Intervention

In this research, the thickness of the gum around the tooth with the implant will be measured. In these procedures to be performed under local anesthesia, some complications due to local anesthesia may occur. Post-operative complications such as edema and bleeding may develop after mechanical treatment.

Participant selection
We invite all patients between the ages of 18-65 who have discomfort such as pain, swelling, bleeding, edema, and gum recession in the implant area to our study.

Voluntary Participation

Your participation in this research is completely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you will receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, procedures will continue to resolve your complaints in the implant area.You may change your mind later and stop participating even if you agreed earlier.

Our study will allow us to see the possible relationship between infection and inflammation in the tissues around the implant and the thickness of the soft tissue. If you have soft tissue that is insufficient to protect your implant, mechanical treatment will attempt to restore the health of the area. Thus, it is aimed to ensure that the implants can remain in the mouth for a longer period of time.

B. Description of the Process

- First, we will ask you to fill out the personal information form. This information includes information such as age, gender, tooth brushing frequency, facial care and education level.
- Your physician will fill in the information section regarding your implants by obtaining information from you and confirmation from the hospital automation system.
- This information is the brand of the implant, the duration of the prosthesis function, the reason for the loss of teeth and the number of implants in the mouth.
- After the information received from you, your physician will place an absorbent paper between the gum and the implant and absorb the gingival fluid into this paper.
- The purpose of this is to determine whether there are biomarkers in this fluid that cause bone destruction.
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- After examining your implants clinically, your gum thickness will be measured with various instruments under local anesthesia and then your implants will be mechanically debrided.
- After non-surgical mechanical treatment, you will be called for a check-up at 1 month, 3 month and 6 month.
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Duration

The research takes 6 months.

Risks

Harms or possible risks that may occur during the research: Complications may develop due to local anesthetic application. Post-operative complications such as edema and bleeding may develop after surgery.
Research-specific risks that may occur during the research: Complications may develop due to local anesthetic administration.

Benefits

Our study will allow us to see the possible relationship between infection and inflammation in the tissues around the implant and the thickness of the soft tissue. If you have soft tissue that is insufficient to protect your implant, it will be thickened and the health of the area will be tried to be restored. If our hypothesis is confirmed, implant treatment will be applied, but soft tissue augmentation procedures will be recommended to clinicians for patients with thin gingiva. Thus, it is aimed to ensure that the implants can remain in the mouth for a longer period of time.

Reimbursements

Your participation is free. You will not be given any other money or gifts to take part in this research

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if

others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except (Alpaslan N.Z.) who will have access to the information, such as research sponsors, Van YYU board, your clinician, etc].)

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following At any time, Assoc.Prof.Dr. I know that I can call Nazlı Zeynep ALPASLAN YAYLI on 04322251747 (work) or 0506 893 11 83 (mobile) or from YYÜ Faculty of Dentistry, Department of Periodontology..

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date_____
Day/month/year

If illiterate

Aliterate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date_____
Day/month/year