Informed Volunteer Consent Form

I-Giving Information about the Research

Responsible researcher Professor at the Faculty of Dentistry, Istanbul University, Faculty of Dentistry, Department of Oral and Maxillofacial Radiology. Dr. İlknur ÖZCAN, this work; With the approval of the ethical committee dated 26/09/2019 and numbered 443, Dt. It is carried out by A. Faruk ERTÜRK.

● Our Dear Volunteer,

● In this study, it was aimed to investigate the reliability of ultrasonographic imaging method in the diagnosis of Temporomandibular Joint (Jaw Joint) Diseases.

● Ultrasonography is a non-invasive (non-invasive) procedure without X-rays and does not contain radiation. It can be applied safely in pregnant women. Unless you are told before the examination, you do not need to make any preparation, starve or use any medication. You can use your medicines on the day and time of the examination. Bring your previously taken images (Panoramic Radiography, Computed Tomography, Magnetic Resonance Imaging, Ultrasonography etc.) with you. It is necessary to comply with the appointment hours given, to be at the appointment place 15 minutes before the appointment time, and if there is no reason to come, you should be informed on 0212 414 20 20 (30324).

● The topics that make up the study content are presented below.

● 1. Demographic Information

● (No personal information is required in the study.)

● 2. Disease Assessments

● 3. Measurement Values After Imaging

● The application takes maximum 15 minutes.

PLEASE READ CAREFULLY!

You have been invited to participate in a clinical trial for scientific research. Before accepting to take part in this study, you need to fully understand the purpose of the study and make your decision freely after being fully informed about the research. This information form has been prepared specifically for you in order to introduce this research in detail. Please read this form carefully. You are free to participate in this research or not. Participation in the study is voluntary. If you agree to participate in the research, you can continue your transactions by signing the form.

NAME OF THE RESEARCH

Investigation of the Reliability of Ultrasonography Use in the Diagnosis of Temporomandibular Joint (Jaw Joint) Diseases: A Prospective (Forward) Study

VOLUNTEER NUMBER

The total number of volunteers envisaged to take part in this research is 100.

PARTICIPATION TIME OF RESEARCH

The period foreseen to take part in this research is 12 months.

PURPOSE OF THE RESEARCH

There are not many studies on the diagnostic value of the use of ultrasonography in the diagnosis of jaw joint diseases in scientific sources. In this study, it is aimed to contribute to the literature (scientific sources) in order to reveal the reliability of the use of ultrasonography in the diagnosis of jaw joint diseases.

THE METHOD OF THE RESEARCH

Joint examination and ultrasonographic examination (USG) will be applied to all volunteers who will participate in the research. In the USG application, when the mouth is open and closed, the right and left joint intervals will be measured and a note will be taken. At the same time, the right and left masseter muscle (chewing muscle) thicknesses will be measured separately at free closing and tight closing, and a note will be taken. The volunteers who will participate in the study will be divided into 4 groups. (I, II, III, IV) For the volunteers in the first group with previously taken MR images, USG and MR findings will be compared. II. EMG and USG results will be compared by applying superficial electromyography (EMG) to the volunteers in the group. III. In volunteers in the group, the values to be obtained by using the USG probe (wired device used in usg shooting) at different angles (horizontal / vertical) will be compared. IV. In the volunteers in the group, the megahertz values (frequency values of the sound vibrations) of the probe (cable device used in usg shooting) are changed and the findings obtained are examined and compared. In addition to evaluating 4 groups separately, at the end of the research, USG data applied to all 4 groups and all findings obtained in joint examination will be compared with each other.

TREATMENTS TO BE APPLIED IN THE RESEARCH

No treatment method will be applied in the research. It is a purely diagnostic study.

POSSIBLE BENEFITS EXPECTED FROM RESEARCH

It is thought that the efficacy and reliability of ultrasonography in the diagnosis of temporomandibular joint (jaw joint) diseases will be revealed and disadvantages in MR and other imaging methods will be eliminated. Our volunteers will be informed about this situation when there is no clinical benefit targeted in terms of volunteers regarding the benefits expected from the research.

POSSIBLE RISKS / LOSSES EXPECTED FROM RESEARCH

Ultrasonography is a non-invasive (non-invasive) procedure that does not contain X-rays and it can be applied safely even in pregnant women since it does not contain radiation. Therefore, the methods to be applied in the research do not pose any risk.

II-Giving Information About Volunteer's Rights

COST OF EXPENSES AND PAYMENTS

You will not be charged any fees for participating in this research or for any expenses that may arise from the research.

INSTITUTION SUPPORTING RESEARCH

The institution supporting the research is Istanbul University Scientific Research Projects Unit (BAP).

WHETHER OR NOT ANY PAYMENT WİLL BE MADE TO THE VOLUNTEER

No material contributions will be made to you or your legal representatives.

PRIVACY OF INFORMATION

Information about you obtained during the research will be recorded with a unique code number. No personal information will be asked from you (TC Identity Number etc.) The results of the research will be used for scientific purposes only. Even if the research is published, your credentials will not be given. However, if necessary, the audience of the research,

attendants, ethical committees and officials will be able to access your information. When you want, you will be able to access your own information after analyzing the data.

Voluntary responsibilities and conditions for exclusion from research

If you disrupt the research program and provide deliberate incorrect information, the researcher may remove you from the research without your permission. However, if you are excluded from research, medical data about you may be used for scientific purposes, keeping your identity confidential.

REJECTING OR DISCONNECTING PARTICIPATION IN THE RESEARCH

Taking part in this research is entirely up to you. You can refuse to take part in the research or leave the research at any stage; If you refuse to take part in the research or give up after participating, you can use medical data about you for scientific purposes, keeping your identity confidential.

Statement of the Volunteer

Mr. Dt. A. Faruk ERTÜRK stated that a medical research will be carried out in Istanbul University Faculty of Dentistry, Department of Oral and Maxillofacial Radiology, and the above information about this research was conveyed to me. After this information, I was invited to such a research as a "volunteer". I believe that if I participate in this research, the confidentiality of my information that I should stay with the physician will be approached with great care and respect during this research. I was given sufficient confidence that my personal information will be protected with utmost care during the use of research results for educational and scientific purposes.

I can withdraw from the research without showing any reason during the execution of the project. (However, I am aware that it would be appropriate for me to notify in advance that I will withdraw from the research in order not to leave the researchers in a difficult situation).

I do not assume any monetary responsibility for the expenditures for the research. I will not receive a payment

Necessary assurance was given that any medical intervention would be provided if any health problems that may arise due to the research application, whether direct or indirect, occur. (I will not be under a monetary burden regarding these medical interventions.)

When I encounter a health problem during the research; at any hour, Dt. I know that I can call A. Faruk ERTÜRK from IU Faculty of Dentistry, Oral, Maxillofacial Radiology AD-0505 782 88 44.

I do not have to participate in this research and may not participate. I have not encountered compelling behavior to participate in the research. I also know that if I refuse to participate, this will not harm my medical care and my relationship with the physician.

I understand all the explanations made to me in detail. I decided to take part as a “volunteer” in this research project that was mentioned at the end of a certain thinking period on my own. I accept the invitation on this matter with great satisfaction and volunteerism.

A copy of this signed form paper will be given to me.

VOLUNTEER APPROVAL FORM

I have read the text above, which shows the information to be given to the volunteer before research. I have been given written and verbal explanations about these. Under these circumstances, I agree to participate in this clinical trial with my own consent, without any pressure or coercion.

Volunteer's Name-Surname / Signature / Date / Address (phone number, fax number, if any ...)

A competent researcher in the research team

Name-surname / Signature / Date

If necessary, the name-surname / signature / date / address of the person who witnessed the transaction (phone number, fax number, ... if any)

Name-surname / signature / date / address of the legal representative if necessary (telephone number, fax number, ...)