PATIENT INFORMED VOLUNTEER WILL FORM EXAMPLE *

Investigation of the Effects of Bisphosphonate on the Gingival Crevicular Fluid Levels of Sclerostin and the DKK-1 in Individuals with Postmenopausal Osteoporosis with Periodontal Changes

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NAME OF THE RESEARCH (OPEN NAME OF THE STUDY):
Investigation of the effect of bisphosphonate use on levels of sclerostin and DKK-1 levels in gingival crevicular fluid of patients with postmenopausal osteoporosis with periodontal changes

Initials of the volunteer's name and surname << >>

You are asked to participate in a research study. Before deciding whether you want to participate, it is important that you understand why the research was conducted, how your information was used, what the study involved, and the possible benefits, risks, and discomfort. If you are involved in another study, you cannot take part in this study.

DO I HAVE TO PARTICIPATE IN THIS STUDY?

The decision whether or not to participate is entirely up to you. If you decide to participate in the study, you will be given this Informed Volunteer Consent Form to sign. If you decide to participate, you are free to leave the work at any time. This will not affect the standard of treatment you receive. If you wish, your doctor / family doctor will be informed of your participation in this clinical trial. In addition, if the supporting company decides to terminate the work, you will also be excluded.

WHAT IS THE SUBJECT AND PURPOSE OF THE STUDY?

The subject of our "Investigation of the effect of bisphosphonate use on levels of sclerostin and DKK-1 levels in gingival crevicular fluid of patients with postmenopausal osteoporosis with periodontal changes" study: The effect of bisphosphonate used for bone resorption on bone metabolism and oral tissues.
The aim of this study was to investigate the effect of bisphosphonate on the jawbone and gingival health. For this purpose, we found it appropriate to investigate two molecules called sclerostin and DKK-1 which show bone resorption.

WORKING PROCEDURES:

Records will be taken from the vicinity of the teeth, which allow us to measure dental calculus, gingival bleeding and health. These procedures are routinely performed in our clinic using a special probe to determine the gingival disease status for each patient. After these records are taken, painless and non-anesthetic paper strips will be examined using the liquid collection process will be done around the teeth. Routine radiographic x-rays will be taken for radiographic diagnosis. Following the collection of samples and recording of patient data, routine dental calculus cleaning for routine periodontal treatment, tooth brushing and interface cleaning will be explained and oral hygiene habits will be improved. The collection of the molecules to be examined (sclerostin and DKK-1) in the gingival gut fluid and recording of the clinical values will be continued and recorded at the end of the 4th week, the 6th month and the 12th month. Samples and data of the control group will be taken only on the day they apply to the clinic.

WHAT DO I NEED TO DO?

You should be willing to follow your doctor's instructions, participate in appointments and visits, and follow all procedures related to the work described above. You must come to visit your labor doctor on designated days and your next visit should be planned before you leave. It is also important that you tell the physician of any other medical treatment you have received before or during the study.

WHAT ARE THE POSSIBLE SIDE EFFECTS, RISKS AND DISABILITY OF MY PARTICIPATION?

There is no side effect, risk or discomfort to your participation.

PREGNANCY AND BIRTH CONTROL

If the subject / patient is a breastfeeding woman, she will be excluded.

WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATION?

In this study, with the regular follow-up of the patients, the possible side effects of osteoporous disease and bisphosphanate treatment on the oral tissues will be determined and prevented from the side effects. In addition, regular dental and gingival checks and treatments will ensure that your oral and dental health is fully ensured and your regular records and treatments will continue in the future.

VOLUNTEER PARTICIPATION

I decide to participate in this research completely voluntarily. I am aware of the fact that I can refuse to participate in this study, or that I can leave at any time, without being affected and without any responsibility. If I leave the study at any time, I will discuss with my doctor the reasons for my separation, the consequences of my separation and the treatments I will receive in the following period.

WHAT IS THE COST OF MY PARTICIPATION?

Labor doctor visits and all laboratory tests related to the study will be covered by the study sponsor and will not be paid to you or your private insurance or official social security institution. If any side effects or physical damage develop, immediately inform your work physician so that the necessary medical treatment can be performed.

HOW WILL MY PERSONAL INFORMATION BE USED?

By signing this form, you consent to your doctor and his / her staff collecting and using your personal information ("Study Data onun) for the study. This is your date of birth, your gender, your ethnicity, and your consent to the use of your study data does not have a designated unit date, but you can discontinue your consent at any time by informing your doctor.

The study data shared with the sponsor will be protected using a code number (olan Code "), which is a unique number for you. The code key required to access your study data is under the

supervision of your doctor. Persons appointed by the study sponsor firm regulatory authority or other supervisory bodies may review your study data held by your doctor.

Your doctor will use your study data for the study. Supporting firm; use your study data to conduct the study, diagnostics and develop medical aid. Both the institution where your doctor is working and the supporting company are responsible for managing your work data in accordance with applicable data protection laws.

The work sponsor may share your work data with other companies, service providers, contracted companies and other research organizations in its own group that will use it only for the purposes mentioned above. The results of the study may be published in medical publications, but your identity will not be disclosed in these publications.

You have the right to request information from your doctor or study sponsor about your collected study data. You also have the right to request that any errors in this data be corrected. If you have a request, please contact your doctor who may be able to help you contact your study sponsor.

If you give up your consent, your doctor will no longer be able to use or share your study data with others. The work sponsor may continue to use your previous work data without giving up your consent.

By signing this form, I consent to the use of your study data as described in this form.

PERSONS THAT CAN BE REACHED IN 24 HOURS DURING THE RESEARCH:
Name, Surname and telephone numbers

CONDITIONS REQUIRED TO LEAVE FROM THE WORK

During work,

1- The emergence of other systemic diseases other than bone resorption and diseases that are known to increase the risk of periodontal disease and which are thought to affect the results of the study (such as diabetes, leukemia, neutropenia, agranulocytosis, obesity, renal failure, immunosuppression for any reason)
2- Corticosteroid, estrogen, phenytoin, cyclosporine, nifedipine use
3- Smoking
4- Being treated in another center
5- Failure to comply with regular follow-up and scheduled treatment dates

HOW NEW INFORMATION CAN IMPACT THE ROLE IN THE WORK

All new information that has emerged while the work is in progress will be communicated to me immediately.

Confirmation of Participation

I have read all the explanations on the Informed Volunteer Consent Form. The written and oral explanation of the above-mentioned subject and purpose of the research was given to me by the physician named below. I know that I voluntarily participate in the research, that I can leave the research at any time, with or without justification, and that I can be excluded from the research by the researcher regardless of my own will.
I agree to participate voluntarily without any pressure or coercion. My doctor gave me a copy of this document for me to keep, including the points I will pay attention to during the study.

Name / Surname / Signature / Date of the Disclosure

Name / Surname / Signature / Date of Person Witnessing Consent if necessary

Name / Surname / Signature / Date of Legal Representative if necessary