INFORMED CONSENT FORM

Title: Evaluation of the Effects of Dexamethasone-Enriched Platelet-Rich Fibrin on Postoperative Pain, Edema, and Trismus Following Impacted Mandibular Third Molar Surgery: A Randomized Split-Mouth Clinical Trial

Principal Investigator: Dr. Muhammet Caner Dere

NCT Number: Not yet assigned.

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Dear Participant,

This study is a scientific research project entitled **"Evaluation of the Effects of Dexamethasone-Enriched Platelet-Rich Fibrin Obtained from Blood on Postoperative Pain, Edema, and Trismus in the Extraction Site of Impacted Third Molar Teeth."**

The purpose of this study is to evaluate the effects of platelet-rich fibrin (PRF), obtained from blood enriched with the corticosteroid drug dexamethasone, applied to the extraction socket of impacted third molar teeth, on postoperative pain, swelling, and mouth opening. Participation in this study is voluntary. Before deciding, we would like to inform you about the study. After reading and understanding this information, if you wish to participate, please sign this form.

In this study, after extraction of an impacted third molar tooth, platelet-rich fibrin — a biologically compatible material derived from your own blood known to promote wound healing and commonly used in oral surgery — will be placed into the extraction socket. On one side, standard PRF will be applied, while on the other side, PRF prepared from blood enriched with dexamethasone (a corticosteroid used in oral surgery to reduce postoperative swelling and limited mouth opening) will be applied. Follow-up visits will be scheduled on the operation day and postoperative days to measure swelling and mouth opening. You will be asked to attend a total of seven visits, and 16 volunteers including yourself will participate in the study. The total duration of participation will be approximately two weeks, with about two hours spent at the clinic and the rest at home.

Your responsibilities during this study include attending all scheduled appointments on time, answering the researcher's questions accurately, following postoperative care instructions, maintaining oral hygiene, and reporting the results to the researcher on time.

There are no additional risks in this study beyond those normally associated with impacted third molar extraction. Expected benefits include reduction of postoperative pain, swelling, and limited mouth opening through the application of PRF with or without dexamethasone, which may provide a more comfortable recovery period. Since medications used during and after surgery may pose risks during pregnancy, you must inform the researcher if you are pregnant or suspect pregnancy. You will be excluded from the study if you have systemic diseases affecting general health, allergies to the medications used, or if you have used corticosteroids within the last month.

If you agree to participate, after being examined by Research Assistant Dr. Muhammet Caner Dere and found suitable, your impacted third molar extraction will be performed in our clinic's local operating room. A physician appointed by Dr. Dere will examine and record swelling and mouth opening measurements. With your permission, approximately 18 ml of blood (1–2 tubes) will be drawn from your arm to prepare the platelet-rich fibrin by centrifugation. Apart from this, standard surgical

procedures for impacted tooth extraction will be followed. After the procedure, antibiotics, painkillers, and mouth rinses will be prescribed as routine infection control.

Possible risks from blood drawing include: 1) mild pain due to needle insertion; 2) small risk of prolonged bleeding or infection.

Swelling will be measured with a flexible ruler at reference points on your face before surgery and on postoperative days 1, 3, and 7. Mouth opening limitation will be measured with a ruler between upper and lower central incisors at the same time points. You will record your pain level at home at 24, 48, and 72 hours post-surgery on a 0–10 scale (0 = no pain, 10 = unbearable pain) and note the amount of analgesics used. Differences between dexamethasone-containing and standard PRF on postoperative pain, edema, and trismus will be evaluated.

You will be informed immediately of any new information that may affect your participation. For questions or concerns regarding the study, adverse effects, or other problems, you can contact Research Assistant Dr. Muhammet Caner Dere at +90 506 440 5864.

All examinations, tests, and medical care related to this study will be provided free of charge. If any health problems arise due to participation in this study, all necessary medical care will be provided without cost and without using your social security.

Participation is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits. If you refuse participation, routine extraction will be performed without PRF application. Failure to comply with study procedures or treatment may result in exclusion from the study. Results will be used for scientific purposes only; your medical data will not be used if you withdraw or are removed.

All your personal and medical information will be kept confidential. Your identity will not be disclosed in any publication. Authorized monitors, auditors, ethics committees, and official authorities may access your medical records when necessary. You may request access to your medical information at any time.

Consent to Participate

I have read and understood the above information. I have had the opportunity to ask questions, and all my questions have been answered satisfactorily. I voluntarily agree to participate in this study, authorizing the researcher to review, transfer, and process my medical data related to this research without any coercion or pressure.

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

Participant:
Name-Surname:

Address:

Phone:

Date and Signature:

Researcher Providing Explanation:

Name-Surname: Muhammet Caner Dere

Title: Research Assistant Dentist

Address: Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cumhuriyet University

Phone: +90 506 440 5864

Date and Signature:

Witness to Consent Process:

Name-Surname:

Title:

Address:

Phone:

Date and Signature: