

Department of Periodontics

School of Dental Medicine

University of Belgrade

Effect of Injectable Platelet-Rich Fibrin (i-PRF) in Initial Treatment of Chronic Periodontitis

NCT04178590

26 April, 2020

Participant Information Sheet

You are invited to participate in the clinical trial called: “Effect of Injectable Platelet-Rich Fibrin (i-PRF) in Initial Treatment of Chronic Periodontitis”. The research includes the assessment of clinical parameters, microbiological and biochemical research of gingival crevicular fluid (GCF) before and after chronic periodontitis therapy: scaling and root planing (SRP) or scaling and root planing (SRP) with application Injectable Platelet-Rich Fibrin (i-PRF). The study protocols was approved by the Ethics Committee of the School of Dental Medicine, University of Belgrade (36/11) and is in compliance with Helsinki Declaration.

The aim of the study is to establish the way in which the parameters change before and after the conventional therapy with or without adding i-PRF, and to show whether there is difference in the treatment.

The patients will be enrolled in the study according to the following inclusion criteria: adults (age between 20 and 75 years), without systemic and/or other oral disease or ongoing drug therapy, which might have an impact on the clinical signs and symptoms of periodontitis, and the presence of minimum 6 teeth per quadrant. The patients who have not received any antibiotic, anti-inflammatory and immunosuppressive therapy in the previous 6 months can be included in this trial; as well as those who have not had any periodontal treatments within the last 12 months.

Current or former smokers, and women who are pregnant or lactating cannot be included in the trial.

After clinic examination and establishing certain parameters patients will be thoroughly instructed on self-performed oral hygiene consisting of: the use of the modified Bass brushing technique, a soft manual toothbrush, a regular toothpaste twice a day, and the use of inter-dental brushes once a day. After taking GCF samples with paper points, safe and painless procedure, a full-mouth SRP will be conducted using ultrasonic scaler and hand instruments (Hu-Friedy, Chicago, IL) under local anesthesia in one or two sessions during the period of 24 hours. It will be also necessary to take two 10 ml tubes of blood and centrifuge it for 3 minutes for i-PRF preparation. I-PRF application will be performed only once at the beginning of the therapy in the periodontal pocket of one side of the jaw, while saline will be applied on the opposite side. The standard of oral hygiene will be checked at each examination after 1, 3 and i 6 mounts, along with taking GCF samples.

Inform consent

I confirm that I have read and understood the information about the project as provided in the Participant Information Sheet.

I confirm that I have had the opportunity to ask questions and the investigator has answered all the questions about the study.

I understand that my participation is voluntary and that I am free to withdraw from the project at any time.

Failure to participate in this study will not affect the therapy required and thus I will not be denied my legal rights as a patient. With my voluntary consent to participate in this research, I will not gain any personal or material gain.

Participant:

Principal Investigator:

Signature of Participant

Signature of Principal Investigator

Date: ____ (dd) ____ (mm), 20__