جـامعة بيروت العربية
BEIRUT ARAB UNIVERSITY

# Efficiency of Hyaluronic Acid Versus Red Injectable Platelet-Rich Fibrin (i-PRF) in Treatment of Stage III Periodontitis (Randomized Controlled Clinical Trial)

**February 23, 2022**

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# Informed Consent Form [Form H-V(A)]

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| **Principal Investigator** | : | Prof. Nayer Aboelsaad |
| **Study Title** | : | Efficiency of Hyaluronic Acid Versus Red Injectable Platelet-Rich Fibrin (i-PRF) in Treatment of Stage III Periodontitis (Randomized Controlled Clinical Trial) |
| **Date** | : | 23/02/2021 |

## PURPOSE OF RESEARCH STUDY

- The purpose of this research study is to compare the clinical efficiency of hyaluronic acid as an adjunct for scaling and root planning to the red injectable platelet-rich fibrin in the non-surgical treatment of stage III periodontitis
- We anticipate that approximately *75* people will participate in this study.

## PROCEDURES

- Selected patients will be referred to the Department of Periodontology, Faculty of dentistry, Beirut Arab University in Lebanon for periodontal treatment
- A complete medical and dental histories will be collected from each patient using a designed study form.
- Ethical clearance is to be obtained from Beirut Arab University and patients' written consents will be collected before starting the clinical trial.
- This comparative prospective randomized clinical trial will be done over a period of 12 weeks (3 months). It will include 75 participants, aged between 20 and 60 years.
- A computerized randomization, **Randomizer.org**, will be used to allocate these patients in three groups (15 patients each):
  **group 1 (G1):** 25 patients will be treated with hyaluronic acid gel as an adjunct to scaling and root planning by applying **1 ml of 0.8% HA** to the base of the pocket (subgingivally) and **0.2 ml of 0.2% HA** topically (applied by the patient).
  **group 2 (G2)**: 25 patients will be treated with red injectable PRF as an adjunct to scaling and root planning.
  **group 3 (G3)**: 25 patients will be treated with scaling and root planning only.
- Before baseline examination, full mouth supragingival scaling and root planing is to be done as well as oral hygiene instructions (the modified Bass brushing technique, a soft toothbrush, regular toothpaste twice a day, and inter-dental cleaning with inter-dental brushes once a day.)

## RISKS/DISCOMFORTS

- All participants in this study (having stage III periodontitis), regardless of the group they'll be associated with, are expected to have improvement in their condition (increase in the clinical attachment level and decrease in the probing pocket depth)

## BENEFITS

- Participants enrolled in this clinical trail will benefit from the free treatment fees for their advanced periodontitis condition. If they seek the same treatment at any other dental office, it will really be expensive.

## VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

- Your participation in this study is entirely voluntary: You choose whether to participate. If you decide not to participate, there are no penalties, and you will not lose any benefits to which you would otherwise be entitled.
- If you choose to participate in the study, you can stop your participation at any time, without any penalty or loss of benefits. If you want to withdraw from the study, please inform directly the researcher(s) who's working with you or send a message to the following number: Dr. Toleen Mazloum: 71/ 201 242
- If we learn any new information during the study that could affect whether you want to continue participating, we will discuss this information with you.

## CIRCUMSTANCES THAT COULD LEAD US TO END YOUR PARTICIPATION

- Under certain circumstances we may decide to end your participation before you have completed the study. Specifically, we may stop your participation, if we determine that it would be unsafe for you to continue in the study (for example if a female participant gets pregnant or if a participant have allergy to the medication we're providing)
- There may also be other circumstances that would lead us to end your participation.

## ALTERNATIVES TO PARTICIPATION

- Participants in this clinical trial will benefit from the free treatment provided for their advanced periodontitis condition.
- The same treatment could be provided at some other dental offices but it will be expensive.

## CONFIDENTIALITY

Any study records that identify you will be kept confidential. The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the BAU Institutional Review Board. (All of these people are required to keep your identity confidential). Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.
Participants' names will be substituted by code numbers on data sheets, and the records are to be kept in a locked drawer in the researcher's office.

## COMPENSATION

You will not receive any payment or other compensation for participating in this study.

**IF YOU HAVE QUESTIONS OR CONCERNS:**

You can ask questions about this research study now or at any time during the study, by talking to the researcher(s) working with you or by calling Dr. Toleen Mazloum at 71/ 201 242. If you have questions about your rights as a research participant or feel that you have not been treated fairly, please call the BAU Institutional Review Board at 00961 1 300110 ext. 2743.

## IF YOU ARE HARMED BY PARTICIPATING IN THE STUDY

- If you feel that you have been harmed in any way by participating in this study, please call Dr. Toleen Mazloum at 71/ 201 242. Please also notify the BAU IRB at 00961 1 300110 ext. 2743 or 2689.

- This study does not have any program for compensating or treating you for harm you may suffer as a result of your participation

## 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 the information in this consent form. 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.

## WHAT YOUR SIGNATURE MEANS

Your signature below means that you understand the information in this consent form.

Your signature also means that you agree to participate in the study.

**Participant Name** : .....

**Contact (phone number)** : .....

**Participant's Signature** : .....

**Date** : .....

**Name of Person Obtaining Consent** : .....

**Signature of Person Obtaining Consent** : .....

**Date** : .....