جـامعة بيروت العربية
BEIRUT ARAB UNIVERSITY

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

Principal Investigator	:	Ali issa, Nour alaaedine, Hadi zahr, May saab, Nayer aboelsaad
Study Title	:	Clinical efficacy of flurbiprofen 2.5% in comparison to 98% Aloe Vera gel as adjunctive therapy in the initial treatment of stage III chronic periodontitis in smoking patients.
Date	:	30/9/2022

PURPOSE OF RESEARCH STUDY

This study aims to evaluate clinically the effect of flurbiprofen gel in comparison to Aloe Vera gel as adjunctive to SRP in the reduction of periodontal pockets in patients with chronic periodontitis stage III in smoking patients.

We anticipate that approximately 60 people will be participating In this study.

PROCEDURES

- on 2-4 sessions, by hand and ultrasonic instrumentation, with oral hygiene instructions reinforcement and proper brushing technique (modified Bass technique) instructions. Note that patients received the same toothbrushes, toothpaste, and interdental brushes. Oral hygiene was reinforced at every visit.
- The selected patients were allocated into three groups (each containing 20) with the help of a computerized randomizer (Randomizer.org), and using a split mouth design, sites were randomly allocated for each patient into either test or control group using a coin flip method:
  - Group one (G1): comprised of 20 patients who received treatment involving the application of flurbiprofen gel as an adjunct to scaling and root planing. Specifically, on the test site of each patient, one milliliter of 2.5% flurbiprofen gel was applied, while on the contralateral side, scaling and root planing were performed as the control intervention.
  - Group two (G2): comprised of 20 patients who received treatment involving the application of aloe Vera gel as an adjunct to scaling and root planing. Specifically, on the test site of each patient, one milliliter of 98% aloe Vera was applied, while on the contralateral side, scaling and root planing were performed as the control intervention.
  - Group three (G3): The intervention involved applying flurbiprofen gel on one site, while the contralateral side received an application of 98% aloe vera.

RISKS/DISCOMFORTS

The risks associated with participation in this study are no greater than those encountered in daily life or during the performance of routine physical or psychological examinations or tests].

BENEFITS

- The patient will benefit for the advantages of scaling and root planing; the patient may benefit from

reducing the clinical attachment loss since the test groups are recommended treatments of chronic periodontitis

- This study may benefit the community if the results came out as positive results, since chronic periodontitis is very common among patients in Lebanon and all around the world, there could be another way of treating chronic periodontitis in a non-surgical manner.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

- Your participation in this study is entirely voluntary. You choose whether to participate or 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, you should inform the investigator prior to withdrawing.
- There are no consequences for the participant if he chooses to stop participating in the study.
- 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

- our participation in this study is entirely voluntary. You choose whether to participate or 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, you should inform the investigator prior to withdrawing.
- There are no consequences for the participant if he chooses to stop participating in the study.
- 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.

ALTERNATIVES TO PARTICIPATION

- Under certain circumstances, we may decide to end your participation before you have completed the study. Specifically, we may stop your participation, if any of the exclusion criteria applies to you during the study which include:
  - Patients with systemic illnesses such as diabetes mellitus or conditions that could potentially impair wound healing were excluded from participation. Additionally, individuals who were pregnant or lactating were not considered for inclusion in the study. Subjects who had been prescribed systemic antibiotics or non-steroidal anti-inflammatory drugs (NSAIDs) within the three months preceding the study were also excluded. Furthermore, individuals with confirmed or suspected

hypersensitivity to Flurbiprofen or aloe Vera, the focus of the investigation, were not included in the study population. These stringent exclusion criteria aimed to control for potential confounding factors and establish a well-defined and relevant patient group for the research analysis.

CONFIDENTIALITY

- Collected data will be stored in folders that will be kept in locked cabinets with access available only to investigators. Electronic data will also be saved in a password protected computer to ensure that only the investigators can have access to the information. 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.

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 Ali Issa (principal investigator] at 76/847506. 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 or 2689

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 : .....