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Effectiveness of a minimally invasive non-surgical approach in the treatment of periodontitis (teeth-supporting tissues infection)

Submission date
07/10/2022

Recruitment status
No longer recruiting

Registration date
18/10/2022

Overall study status
Completed

Last Edited
18/10/2022

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Periodontitis is a chronic inflammatory disease associated with plaque accumulation and characterized by the progressive destruction of the tooth-supporting tissues which may result in tooth loss. A gap between the tooth and gum will occur which can accumulate germs and deposits. Subgingival debridement (cleaning the root surface by using specific instruments) is effective in treating periodontitis. However, it is technically demanding, and complete cleaning is difficult to achieve. More hard deposits are generally detected in deep sites (periodontal depth > 5 mm), which limits the efficacy of closed subgingival debridement as definitive therapy.

A minimally invasive non-surgical therapy (MINST) using tiny instruments was proposed for the treatment of deep periodontal pockets. Comparable clinical outcomes have been achieved using this approach compared to the surgical ones. To the limits of our knowledge, no study compared MINST to the traditional subgingival instrumentation (larger standard instruments).

For patients with periodontal pockets of 6 mm or more (population), this study aims to understand what the effect of minimally invasive non-surgical therapy (intervention) is compared to traditional subgingival instrumentation (comparison) in improving the clinical attachment level between the tooth and gum (CAL) (primary outcome).

Who can participate?
Healthy adults with periodontitis stage III

What does the study involve?
This study involves using non-surgical periodontal instruments. On Day 1, participants will be examined and receive teeth descaling, oral hygiene instructions and an impression of their teeth will be taken in order to make a stent with grooves for the probe. After 2 weeks, various periodontal indices will be recorded using a dental probe. If the Full-Mouth Plaque Score (FMPS) is less than 20%, the patient can be enrolled in the study. The test group will receive treatment

following the minimally invasive non-surgical approach and the control group will receive treatment using the traditional subgingival instrumentation.

What are the possible benefits and risks of participating?
Non-surgical periodontal therapy is essential for the treatment of periodontitis. However, it may cause teeth hypersensitivity (mostly within the first two weeks), and gingival recession (due to the trauma caused by the instruments).

Where is the study run from?
Periodontology Department, Faculty of Dental Medicine, Damascus University (Syria)

When is the study starting and how long is it expected to run for?
January 2021 to June 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Hussam Hassan
hussam.perio@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Hussam Hassan

ORCID ID
https://orcid.org/0000-0001-8239-8769

Contact details
Damascus Countryside
Sahnaya
Fares Al-Koury Street 12
Damascus Countryside
Syria
None available
+963934856114
hussam.perio@gmail.com

Additional identifiers

Study information

Scientific Title
Efficacy of minimally invasive non-surgical approach in the initial therapy of stage III Periodontitis: a randomized controlled trial

Study objectives
Minimally invasive non-surgical therapy can provide a better clinical attachment level gain and less gingival recession compared to traditional subgingival instrumentation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study is registered at Damascus University in order to get a Master's degree in periodontology. This study did not require an ethical approval because the treatment provided is considered as a basic treatment for periodontitis. However, an ethical approval is now available.

Approved 01/06/2022, the Medical Trial Ethics Council (MTEC) in Damascus University (PO Box 30621, Damascus, Syria; +963 (11) 339 23223; dl.srd@damascusuniversity.edu.sy), ref: DN-01062022-5

Study design
Interventional double-blind split-mouth randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stage III periodontitis with deep periodontal pockets

Interventions
Day 1:
1. Examination
2. Supragingival scaling
4. Oral hygiene instructions
5. Impression taking in order to make a stent with grooves for the probing

After 2 weeks:
Periodontal indices recording using UNC 15 probe: (CAL, PD, BOP, REC, KGw, gingival phenotype, FMBS, FMPS).
If the Full-Mouth Plaque Score (FMPS) is less than 20%, the patient can be enrolled in the study. Randomization will be made by flipping a coin twice, first to decide which side will receive the treatment first, and the second coin flip will be to decide the intervention to be applied. The first intervention will be made at the same appointment. After one week, the second intervention will be made on the other side.

Test group:
Minimally invasive non-surgical approach
Micro mini five Gracey curettes (Hu-Friedy) and thin ultrasonic tips (Woodpecker) will be used. 3.5x Loupes will be used.

Control group:
Traditional subgingival instrumentation using standard Gracey curettes (Zeffiro) and standard ultrasonic tips (Woodpecker).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Clinical attachment level (CAL) recorded at a scheduled visit after 3 months

Key secondary outcome(s))
1. Probing depth (PD) measured using a periodontal probe at a scheduled visit after 3 months
2. Gingival recession (REC) measured using a periodontal probe at a scheduled visit after 3 months
3. Bleeding on probing (BOP) measured using a periodontal probe at a scheduled visit after 3 months
4. Closed pockets percentage (4 mm or less with no bleeding on probing) measured using a periodontal probe at a scheduled visit after 3 months

Completion date
01/06/2023

Eligibility

Key inclusion criteria
1. Good general health
2. Able to provide voluntary written approval
3. Aged 18 years old and over
4. Have periodontitis stage III
5. Have periodontal pockets of 6 mm or more on both sides of the same arch
6. Have less than 20% of FMPS (Full Mouth Plaque Score)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Systemic diseases that interfere with the healing of periodontal tissues (diabetes, Hyperparathyroidism, etc.)
2. Life-threatening diseases
3. Pregnancy or breastfeeding
4. Heavy smokers (more than 20 units a day)
5. Furcation involvement at the same area to be treated
6. Tooth mobility
7. Periodontal treatment in the last 12 months
8. Patients who showed no sign of corporation in terms of good oral hygiene
9. Radiation therapy
10. Alcoholics
11. Drugs that interfere with periodontal healing

Date of first enrolment
04/04/2022

Date of final enrolment
01/03/2023

Locations

Countries of recruitment
Syria

Study participating centre
Faculty of Dental Medicine
Damascus University
Periodontology Department
PO Box 30621
Damascus
Syria
None available

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			18/10/2022	No	Yes
Protocol file	version 1.0	21/04/2021	18/10/2022	No	No