Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of 980 nm diode laser along with modified Wiedemann flap surgery on periodontal parameters in patients with chronic periodontitis

Protocol summary

Study aim
Determining the effect of 980 nm diode laser along with modified Wiedemann flap surgery on periodontal parameters in patients with chronic periodontitis

Design
The clinical trial will have a control group with split mouth allocation, with parallel groups, double-blind, phase 3, for 24 patients, for randomization of surgery with laser and without laser by coin toss.

Settings and conduct
This split mouth clinical trial study will be conducted on 24 patients diagnosed with chronic periodontitis with a pocket depth of more than 5 mm who refer to the Gorgan Faculty of Dentistry and need surgery. surgeon is not involved in choosing the side of the quadrant for Modified Widman surgery with or without laser, we will take the help of a coin toss, in this way, one quadrant will be randomly assigned to the control group (modified Widman surgery) and the other side to the case group (surgery Modified Widman will be customized with laser (980 nm). All patients receive phase 1 periodontal treatment including oral hygiene education, scaling and are standardized in this respect. 4 weeks after the 1st phase of the treatment and before the modified Wiedemann flap surgery, all clinical parameters are recorded. This study is double blind. Which quadrant received only surgery and which quadrant received surgery and laser. Clinical parameters are recorded before surgery and 3 and 6 months after surgery for all sites: including PPD (pocket probing depth), CAL (clinical attachment loss), BOP (bleeding on probing), GR (gingival recession) and PI(plaque index).

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with chronic periodontitis with a pocket depth of more than 5 mm, who have at least 20 teeth؛ Exclusion criteria :alcohol, cigarettes, immigration, death

Intervention groups
Intervention: surgery with diode laser Control group: received only surgery

Main outcome variables
PPD، CAL، BOP، GR، PI

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231123060153N1**
Registration date: **2024-06-08, 1403/03/19**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-08, 1403/03/19**
Update count: **0**

Registration date
2024-06-08, 1403/03/19

Registrant information

Name
Amir reza Ahmadinia

Name of organization / entity

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Iran (Islamic Republic of)

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+98 17 3253 6270

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-21, 1403/03/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of 980 nm diode laser along with modified Wiedemann flap surgery on periodontal parameters in patients with chronic periodontitis

Public title
Evaluation of the effect of 980 nm diode laser along with modified Wiedemann flap surgery on periodontal parameters
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic periodontitis with a pocket depth of more than 5 mm Having at least 20 teeth Systemically healthy people
Exclusion criteria:
Patients who are under any drug treatment that affects the periodontium Pregnant or lactating patients Patients who have used antibiotics continuously (one full week) during the last 3 months Patients who consume alcohol Patients who smoke and use tobacco Patients who have received periodontal treatment in the last 6 months The presence of orthodontic appliances or various types of prostheses in the treatment area Non-cooperation of the patient/emigration or death/non-observance of hygiene during the follow-up procedures Suffering from one of the diseases affecting the study process
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **24**
24 patients were treated as the control group and the test group.
Randomization (investigator's opinion)
Randomized
Randomization description
It is a split mouth randomized clinical trial. So that the opinion and desire of the surgeon is not involved in choosing the side of the quadrant for modified Widman surgery with laser and without laser, we will take help from coin toss, so one quadrant will be randomly assigned to the control group (modified Wiedemann surgery) and side Others will be allocated to the case group (Widman's modified surgery with laser (940 nm).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind study, patients and outcome assessors (periodontal parameters) are blinded. The patient will not know in which jaw quadrant he will receive the laser, and neither will the outcome evaluator.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences
Street address
Phalsafi Higher Education Collection،The Beginning of the shast kola Road
City
Gorgan
Province
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Postal code
4934174515
Approval date
2024-04-30, 1403/02/11
Ethics committee reference number
IR.GOUMS.REC.1402.354

Health conditions studied

1

Description of health condition studied
Chronic periodontitis disease
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
PPD (pocket probing depth)
Timepoint
Clinical parameters are recorded before surgery and 3 and 6 months after surgery for all sites
Method of measurement
Williams probe is used to measure clinical parameters

2

Description
CAL (clinical attachment loss)
Timepoint
Before surgery, three months later, 6 months later
Method of measurement
It is measured by a williams probe

3

Description
BOP (bleeding on probing)
Timepoint
Before surgery, 3 months after, 6 months after
Method of measurement
By probing the area and checking the amount of bleeding

4

Description
GR (gingival recession)
Timepoint
Before surgery, 3 months after, 6 months after
Method of measurement
Using William's probe, we check the amount of gingival recession

5

Description
PI (plaque index)
Timepoint
Before surgery, 3 months after, 6 months after
Method of measurement
It is measured by a probe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receive surgical treatment without laser radiation in one jaw quadrant
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Gorgan dental faculty
Full name of responsible person
Amirreza Ahmadinia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Gorgan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Amir reza Ahmadinia
Position
Associate professor
Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available