Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparison of Diplen LX membrane and Coe-pack usage from the patient preference point of view and on the pain and wound healing after the periodontal flap surgery in patients with moderate to severe periodontitis

Protocol summary

Study aim

Comparison of the use of Diplex LX membrane and Coe-pack dressing according to patient preference and on pain and wound healing after periodontal flap surgery in patients with moderate to severe periodontitis

Design

Clinical trial without control group, with parallel groups, without blinding, randomized

Settings and conduct

All patients complete the first phase of periodontal treatment and are evaluated two weeks after the first phase of treatment. Only individuals with an index plaque less than 20% and a probing pocket depth greater than 5 mm in all teeth of at least two quadrants were randomly assigned to one of the two study groups. Patients will be divided into two intervention groups using dice throwing and even and odd numbers. The intervention group 1 will be odd numbers and the intervention group 2 will be even numbers. Blinding will not happen.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with moderate to severe periodontitis will be enrolled. Exclusion criteria: Patients with other systemic diseases, mild periodontitis, smokers, and pregnant women will not be included in the study.

Intervention groups

Intervention group 1: Diplen LX membrane dressing will be used in patients after periodontal flap surgery. Intervention group 2: Coe-pack dressing will be used in patients after periodontal flap surgery.

Main outcome variables

Pain after surgery, Wound healing after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100412003690N10**
Registration date: **2019-10-30, 1398/08/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-30, 1398/08/08**
Update count: **0**

Registration date

2019-10-30, 1398/08/08

Registrant information

Name
Masoomeh Faramarzie
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The comparison of Diplen LX membrane and Coe-pack usage from the patient preference point of view and on the pain and wound healing after the periodontal flap surgery in patients with moderate to severe periodontitis

Public title
Diplen LX membrane and Coe-pack usage from the patient preference point of view and on the pain and wound healing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Moderate to severe periodontitis Consent to participate in the study Under 20 percents plaque index Depth of probing envelope greater than 5 mm
Exclusion criteria:
Pregnant and lactating women Smokers Minor peridontitis

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly divided into two intervention groups using dice throwing and even and odd numbers. The intervention group 1 will be odd numbers and the intervention group 2 will be even numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Tabriz Medical University
Street address
Street camping , Tabriz University of Medical Scienses , Tabriz University of Medical Sciences , Ethics Committee Of Tabriz Medical University
City
Tabriz
Province
East Azarbaijan
Postal code
5166614713

Approval date
2018-10-15, 1397/07/23

Ethics committee reference number
IR.TBZMED.REC.1398.707

Health conditions studied

1

Description of health condition studied
Pain after surgery

ICD-10 code
G89

ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Pain after surgery

Timepoint
3, 7 and 14 days after intervention

Method of measurement
Visual Analogue Scale

2

Description
Wound healing after surgery

Timepoint
7 and 14 days after intervention

Method of measurement
Wound healing index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: All patients complete the first phase of periodontal treatment and are evaluated two weeks after the first phase of treatment. Only those with an index plaque less than 20% and a probing depth of more than 5 mm in all teeth will receive at least two quadrants of L-Diplex membrane dressing.

Category
Treatment - Other

2

Description
Intervention group: All patients complete the first phase of periodontal treatment and are evaluated two weeks after the first phase of treatment. Only those with an index plaque less than 20% and a probing depth of more than 5 mm in all teeth will receive at least two quadrants Coe-pack dressing after surgery in a quadrant.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, IRAN

Full name of responsible person
Masoumeh Faramarzi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Prof. Abolghasem Jouyban

Street address
Floor3, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Masoomeh Faramarzie

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, Iran

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Person responsible for scientific inquiries

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Position
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Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data obtained from the participants can be presented in the form of a table. The protocol for the study, which is routine methods, has no problems with its publication. Statistical analysis can also be provided. In this study, an informed consent form will be used that can be published without mentioning the person's name and personal details. A clinical study report can be made after the necessary analyzes.
When the data will become available and for how long
Start the access period 9 months after publishing the results
To whom data/document is available
For researchers in Dental school of Tabriz University
Under which criteria data/document could be used
For scholars working in other academic and academic institutions, if approved by the project implementer
From where data/document is obtainable
Dr. Masoomeh Faramarzi, email or phone Dental school of Tabriz University, Periodontics department, 9144113420 0098 ، faramarzim@tbzmed.ac.ir
What processes are involved for a request to access data/document
After receiving the request will be answered within a week.
Comments