

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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 Faramarz

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1385 4863

##### Email address

faramarzim@tbzmed.ac.ir

##### 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 periodontitis

**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 Sciences , 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

##### Street address

Golgasht Ave, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

##### Phone

+98 41 3335 5965

##### Email

faramarzim@tbzmed.ac.ir

## 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.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

##### Phone

+98 41 3335 5965

##### Email

faramarzim@tbzmed.ac.ir

##### 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 Faramarzi

##### Position

Associate Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

##### Street address

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

##### City

Tabriz

##### Province

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##### Phone

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##### Fax

+98 41 1334 6977

##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Masoomeh Faramarzi

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##### Latest degree

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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Associate Professor

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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**