

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of guided bone regeneration of collagen-curcumin-aspirin membrane with commercial collagen membrane in patients who needed alveolar ridge augmentation for implant placement

#### Protocol summary

##### Study aim

Comparison of guided bone regeneration of collagen-curcumin-aspirin membrane with commercial collagen membrane in patients who needed alveolar ridge augmentation for implant placement

##### Design

A parallel clinical trial with the control group of 10 patients

##### Settings and conduct

The prepared membranes will be used in 10 patients (each patient needs two implants). After implant placement, the periosteum and skin are sutured using a 5-0 suture. In 1, 2, 4 and 8 weeks after surgery, a clinical evaluation of the patient will be performed. In two months after surgery, the radiographic images will be used to examine the area.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who need implant placement and alveolar ridge augmentation at the same time.

Exclusion criteria: People with poor oral health

##### Intervention groups

Test group: The prepared collagen-curcumin-aspirin membranes are used under the implant. Control group: Commercial collagen membranes are used under the implant.

##### Main outcome variables

Ability to conduct guided bone regeneration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200919048756N2**

Registration date: **2021-01-20, 1399/11/01**

Registration timing: **prospective**

Last update: **2021-01-20, 1399/11/01**

Update count: **0**

##### Registration date

2021-01-20, 1399/11/01

##### Registrant information

###### Name

Solmaz Maleki Dizaj

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3335 3161

###### Email address

maleki.s.89@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-02-02, 1399/11/14

##### Expected recruitment end date

2021-03-04, 1399/12/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of guided bone regeneration of collagen-curcumin-aspirin membrane with commercial collagen membrane in patients who needed alveolar ridge augmentation for implant placement

##### Public title

Evaluation of guided bone regeneration in collagen-curcumin-aspirin membrane

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients who need implant placement and alveolar ridge augmentation at the same time.

### Exclusion criteria:

People with poor oral health Smokers Alcoholics People with diabetes People with high blood pressure or other systemic diseases

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

-

## Randomization (investigator's opinion)

N/A

## Randomization description

## 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 University of Medical Sciences

##### Street address

Golgasht St, Daneshgah Ave, Tabriz University of Medical Sciences, Tabriz, Iran

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

#### Approval date

2020-12-13, 1399/09/23

#### Ethics committee reference number

IR.TBZMED.REC.1399.864

## Health conditions studied

### 1

#### Description of health condition studied

Guided bone regeneration (GBR) to improve bone defects

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

New bone formation

#### Timepoint

Two months after implant and membrane placement

#### Method of measurement

Radiographic imaging

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: One of the patient's implants is considered as a control in which a commercial collagen membrane (Regen, Germany) is placed in the lower tissue of the implant and then the tissue is sutured and the implant is placed. Another implant of the patient is considered as the test group. Collagen-curcumin-aspirin membranes are placed in the lower tissue of the implant and then the tissue is sutured and the implant is placed.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Dentistry, Tabriz University of Medical Sciences

##### Full name of responsible person

Amir Hossein Bani Shahabadi

##### Street address

Golgasht St, Daneshgah Ave, Tabriz University of Medical Sciences, Tabriz, Iran

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a\_banishahabadi@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Vice Chancellor for Research and Technology, Tabriz University of Medical Sciences

**Street address**

Golgasht St, Tabriz University of Medical Sciences, Central Building No. 2 / Third Floor, Vice Chancellor for Research and Technology

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research-vice@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**

Amir Hossein Bani Shahabadi

**Position**

Resident of Oral and Maxillofacial Surgery

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Solmaz Maleki Dizaj

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Nanotechnology

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Solmaz Maleki Dizaj

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Nanotechnology

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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**

No - There is not 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 will be published as an article.

**When the data will become available and for how long**

After the final publication of the article resulting from the data.

**To whom data/document is available**

Public

**Under which criteria data/document could be used**

For use in research articles and systematic reviews with citation.

**From where data/document is obtainable**

Dr. Solmaz Maleki Dizaj, Tabriz Faculty of Dentistry

**What processes are involved for a request to access data/document**

It can be in person or by email.

**Comments**