

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of spongy gelatin membrane containing nanocurcumin and nanohydroxyapatite on bone regeneration and improvement the soft tissue quality in extracted socket: A Clinical Trial

#### Protocol summary

##### Study aim

Effect of spongy gelatin membrane containing nanocurcumin and nanohydroxyapatite on bone regeneration and improvement the soft tissue quality in extracted socket: A Clinical Trial

##### Design

Clinical trial with control group, with parallel groups on 20 patients

##### Settings and conduct

Patients who have split mouth extractions on both sides of the mouth, on the intervention side, the membrane containing nanocurcumin and nanohydroxyapatite inside the cavity and on the control side without membrane, according to routine surgeries, no substance will be placed in the cavity. And then, in the second month after the surgery, the patient will refer to the radiograph to check the area.

##### Participants/Inclusion and exclusion criteria

Entry criteria: patients who need early implants who have healthy buccal and palatal plates. Regarding the health of the buccal and palatal plates, after making sure that the tooth is not retained and explaining it to the patient, a CBCT radiograph is requested from the patient. Exit criteria: Patients with broken buccal or palatal plate during tooth extraction; Patients with periapical lesion; People with very poor oral hygiene; smokers; Alcoholic people; People with diabetes; People with high blood pressure; Other systemic diseases; Patients with age less than 18 years or more than 50 years

##### Intervention groups

Intervention group: patients who had split mouth extractions on both sides of the mouth, on the intervention side, a membrane containing nanocurcumin and nanohydroxyapatite inside the socket. Control group: patients who had split mouth extractions on both sides of the mouth, and on the control side, according to routine surgeries, no material will be placed in the

socket.

##### Main outcome variables

Bone growth and soft tissue repair

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200919048756N5**

Registration date: **2022-12-13, 1401/09/22**

Registration timing: **prospective**

Last update: **2022-12-13, 1401/09/22**

Update count: **0**

##### Registration date

2022-12-13, 1401/09/22

##### 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

2023-03-05, 1401/12/14

##### Expected recruitment end date

2024-03-04, 1402/12/14

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of spongy gelatin membrane containing nanocurcumin and nanohydroxyapatite on bone regeneration and improvement the soft tissue quality in extracted socket: A Clinical Trial

**Public title**

Effect nanocurcumin and nanohydroxyapatite on bone regeneration and improvement the soft tissue

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients who need early implants who have healthy buccal and palatal plates.

**Exclusion criteria:**

Patients with broken buccal or palatal plate during tooth extraction Patients with periapical lesion People with very poor oral hygiene smokers People with diabetes Alcoholic people People with high blood pressure Other systemic diseases

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

**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**

2022-07-31, 1401/05/09

**Ethics committee reference number**

IR.TBZMED.REC.1401.420

**Health conditions studied****1****Description of health condition studied**

bone defects

**ICD-10 code**

K06

**ICD-10 code description**

Other disorders of gingiva and edentulous alveolar ridge

**Primary outcomes****1****Description**

Bone growth and soft tissue repair

**Timepoint**

Two months after placing the membranes

**Method of measurement**

Radiographic imaging

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: patients who had split mouth extractions on both sides of the mouth, on the intervention side, a membrane containing nanocurcumin and nanohydroxyapatite inside the socket.

**Category**

Treatment - Other

**2****Description**

Control group: patients who had split mouth extractions on both sides of the mouth, and on the control side, according to routine surgeries, no material will be placed in the socket.

**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**

Javad Yazdani

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3335 3161

**Email**

maleki.s.89@gmail.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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 3161

**Email**

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**

Javad Yazdani

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 3161

**Email**

maleki.s.89@gmail.com

## 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**

Dentistry

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 3161

**Email**

maleki.s.89@gmail.com

## 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

**Street address**

Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 3161

**Fax****Email**

maleki.s.89@gmail.com

## 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 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**