Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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@gmai.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