

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of the effect of Chitosan biodegradable scaffold in prevention of alveolar osteitis

Protocol summary

Study aim

Evaluation of the effect of Chitosan biodegradable scaffold in prevention of alveolar osteitis following mandibular impacted third molar surgical extraction

Design

Parallel randomized controlled clinical trial with a ratio of 1:1 and with superiority design, double-blind, phase 3 on 176 patients, using blocked randomization method

Settings and conduct

In this clinical trial, patients who referred to oral and maxillofacial surgery department of Kermanshah Dental School for surgery of impacted mandibular third molar will be studied. Two groups that have the inclusion criteria, will be randomly assigned to the intervention group (treatment with Chitosan biodegradable scaffold) and control (routine treatment without Chitosan biodegradable scaffold). In this study, patients and statistician are not aware of the treatment status of the participants. In all patients, tooth extraction is surgically performed routinely and then Chitosan biodegradable scaffold is placed in the sockets of the extracted teeth for the intervention group. Patients will be evaluated for AO on the third and seventh days after surgery.

Participants/Inclusion and exclusion criteria

Patients over 18 years old, needing impacted third molar extraction surgery, who refer to oral surgery department of Kermanshah Dental School; volunteering to participate in this trial.

Intervention groups

In this study, two groups that have the inclusion criteria will be randomly assigned to the intervention group (treatment with Chitosan biodegradable scaffold) and control (routine treatment without the use of Chitosan biodegradable scaffold).

Main outcome variables

Incidence of alveolar osteitis will be compared between the two study groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045516N4**

Registration date: **2021-01-11, 1399/10/22**

Registration timing: **prospective**

Last update: **2021-01-11, 1399/10/22**

Update count: **0**

Registration date

2021-01-11, 1399/10/22

Registrant information

Name

hamed Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3835 2842

Email address

hamed.nazari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Chitosan biodegradable scaffold in prevention of alveolar osteitis

Public title

The effect of Chitosan biodegradable scaffold in prevention of extracted tooth dry socket

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients in need of surgical extraction of the mandibular third molar who refer to oral surgery department of Kermanshah dental school Patients with risk factors for alveolar osteitis (history of pericoronitis, smoking, use of OCPs, history of alveolar osteitis)

Exclusion criteria:

Surgical complications in surgeon's opinion Antibiotic therapy regimen Patients' unwillingness to cooperate with the trial Loss to follow up

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **176**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be divided into two equal groups by using the blocked randomization method and considering the number of samples required from the sample size formula. The process is done using block sizes of 6 and 8. Blocking will already be done by randomization online software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The list of specified intervention groups in this process remains by the coordinator. The dentist who is responsible for assessing the inclusion/exclusion criteria and registration of people will not know about this process. There is a closed envelope for each patient that was located a random 4-digit numerical code on each envelope determines which group the patient is in. Whether each code is specific to what group is written inside a table that was written by someone who have not participated in the process of study. This study is a double-blind clinical trial (in which patients and a statistician have been blinded).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics in Research - Kermanshah University of Medical Sciences

Street address

Committee of Ethics in Research, Vice chancellor for research and technology, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2020-12-22, 1399/10/02

Ethics committee reference number

IR.KUMS.REC.1399.877

Health conditions studied

1

Description of health condition studied

Alveolar osteitis

ICD-10 code

K10.3

ICD-10 code description

Alveolitis of jaws

Primary outcomes

1

Description

Incidence of alveolar osteitis after surgical extraction of mandibular impacted third molars

Timepoint

3rd and 7th days after surgery

Method of measurement

Clinical diagnosis of alveolar osteitis by an experienced oral and maxillofacial surgeon regarding the signs and symptoms including: uncontrollable pain with analgesics between the first and third days to the week after tooth extraction with one or a combination of these signs: absence or insufficient blood clot in the socket, Detritus, exposed alveolar bone with or without halitosis

Secondary outcomes

1

Description

Pain intensity after surgery

Timepoint

3rd and 7th days after surgery

Method of measurement

Using Visual Analogue Scale (VAS)

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

Intervention group: Chitosan biodegradable scaffold is placed in the sockets of the extracted teeth after surgery. (The process of making scaffold is done by using chitosan polymer which is biodegradable. The Chitosan is prepared by Chitin deacetylase.)

Category

Prevention

2**Description**

Control group: Routine treatment without the use of Chitosan biodegradable scaffold is done.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kermanshah University of Medical Sciences - Dental School

Full name of responsible person

Hamed Nazari

Street address

School of Dentistry, Shariati St.

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6713954658

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

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Khodarahmi

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No. 2 Central Building, Kermanshah University of Medical Sciences, Shahid Beheshti Street, Kermanshah, Iran

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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

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Hamed Nazari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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

Kermanshah University of Medical Sciences

Full name of responsible person

Hamed Nazari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Behnam Fatehi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available