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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Reza Khodarahmi
Street address
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
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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
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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