

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of the amount of serum used on the complications after third Molar surgery

Protocol summary

Study aim

Determining the effect of the amount of serum used on the complications after third Molar surgery

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, phase 2, on 300 patients. A random number table will be used for randomization.

Settings and conduct

The aim of this study was to determine the effect of the amount of serum used on complications after third molar surgery. This study is a single blind, randomized clinical trial. The study population is patients undergoing third molar surgery. Patients will receive randomly 20, 40, and 60 ml of normal sterile saline in 3 intervention groups. The patient will be unaware of the group assigned to him.

Participants/Inclusion and exclusion criteria

Inclusion criteria for participants: Patients undergoing mandibular third molar surgery, They should be in the moderate surgical group, The existence of a third mandibular molar, the occlusion of which has been confirmed by panoramic radiography. Exclusion criteria for participants: drug use, alcohol use, smoking, the presence of underlying diseases that interfere with wound healing, such as systemic diabetes, gastrointestinal diseases, kidney disease and heart and lung disease, use of drugs that cause dry mouth.

Intervention groups

Intervention group 1: Patients will receive 20 ml of normal sterile saline. Intervention group 2: Patients will receive 40 ml of normal sterile saline. Intervention group 3: Patients will receive 60 ml of normal sterile saline.

Main outcome variables

Main Outcomes of the Study: Pain and Swelling.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045516N3**

Registration date: **2021-01-02, 1399/10/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-02, 1399/10/13**

Update count: **0**

Registration date

2021-01-02, 1399/10/13

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

2020-12-21, 1399/10/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the amount of serum used on the complications after third Molar surgery

Public title

Effect of serum on the complications of third Molar surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing mandibular third molar surgery They should be in the moderate surgical group. The existence of a third mandibular molar, the occlusion of which has been confirmed by panoramic radiography.
Exclusion criteria:

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients receive a random number using the random number table according to their priority entry to the center that matches the numbers on the sealed envelopes. Inside the sealed envelopes is one of the codes A, B and C. A represents the first intervention group that will receive 20 ml of sterile normal saline, B represents the second intervention group that will receive 40 ml of sterile normal saline, and C represents the third intervention group that will receive 60 ml of normal sterile saline.

Blinding (investigator's opinion)
Single blinded

Blinding description
Study participants are not aware of their assigned group and will be unaware of the amount of serum used. Of course, they participate in the study with informed consent.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research, Building No. 2,
Kermanshah University of Medical Science, Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2020-11-10, 1399/08/20

Ethics committee reference number

IR.KUMS.REC.1399.806

Health conditions studied

1

Description of health condition studied

Mandibular third molar surgery

ICD-10 code

K00.1

ICD-10 code description

Supernumerary teeth

Primary outcomes

1

Description

Pain

Timepoint

Immediately, 2 and 7 days after surgery

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Inflation

Timepoint

Immediately, 2 and 7 days after surgery

Method of measurement

self report

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive 20 ml of normal sterile saline 5 minutes after surgery. The size of the syringe used for rinsing with serum is 20 ml.

Category

Treatment - Drugs

2

Description

Intervention group: Patients will receive 40 ml of normal sterile saline 5 minutes after surgery. The size of the syringe used for rinsing with serum is 40 ml.

Category

Treatment - Drugs

3

Description

Intervention group: Patients will receive 60 ml of normal sterile saline 5 minutes after surgery. The size of the syringe used for rinsing with serum is 60 ml.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental College

Full name of responsible person

Hamed Nazari

Street address

Front of the Post Office, Dr. Shariati St

City

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6713954658

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Email

Nazari.hamed67@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Khodarahmi

Street address

Vice Chancellor for Research, Building No. 2,
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research_it@kums.ac.ir

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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Full name of responsible person

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Position

Assistant 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
Shima Zarie
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)

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

It is accessible to researchers working in academic and scientific institutions for further research.

From where data/document is obtainable

They can request the data by sending an email to Dr. Hamed Nazari. Nazari.hamed67@gmail.com

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

After sending the data request email, study partners will make the decision.

Comments