

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effectiveness of mannitol on postoperative complications after impacted mandibular third molar surgery

Protocol summary

Study aim

Surgical removal of impacted mandibular third molar is one of the most common surgical procedures in the oral cavity which usually accompanies with predictable sequels such as bleeding, swelling, pain and trismus. The aim of this study is to use mannitol and review its relationship with complications such as pain, swelling and trismus

Design

Randomized, double-blind, placebo-uncontrolled, single-center, phase one trial

Settings and conduct

In this split mouth study, 30 patients referred to Hamadan dental school with the age range of 16-64 years old with impacted mandibular third molars who had bilaterally and similar impacts are to be reviewed. At least 4 weeks interval is considered between surgeries on either side to ensure recovery of the surgery. Surgery is implemented by maxillofacial surgeon but the variables were examined by student who is blind to use or non-use of mannitol and for this reason this study is blinded both on the patient and the inspector person

Participants/Inclusion and exclusion criteria

Inclusion criteria: Taking no medications and drugs, healthy patients with ASA 1 category, lack of allergy to local anesthesia, having bilateral mandibular third molar with similar impaction Exclusion criteria: Poor oral hygiene, hypersensitivity to mannitol, smoking and alcohol abuse, pregnant and lactating mothers

Intervention groups

In this study, the side of the mandible where mannitol is infused will be considered as the treatment side while the opposite side is control that is randomly selected for each patient.

Main outcome variables

Pain level is recorded with VAS scale, swelling is evaluated by inflexible tape and trismus is measured by assessing the interincisal distance by digital caliper on 2, 4, 6 and 8 days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160712028892N2**

Registration date: **2019-01-17, 1397/10/27**

Registration timing: **prospective**

Last update: **2019-01-17, 1397/10/27**

Update count: **0**

Registration date

2019-01-17, 1397/10/27

Registrant information

Name

Omid Soltaninia

Name of organization / entity

dental school, Hamadan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 38381058

Email address

omid.soltaninia@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-01, 1397/11/12

Expected recruitment end date

2020-01-16, 1398/10/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of mannitol on postoperative complications after impacted mandibular third molar surgery

Public title

Effectiveness of mannitol on postoperative complications after impacted mandibular third molar surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Taking no medications and drugs Healthy patients with ASA 1 category Lack of allergy to local anesthesia; Having bilateral mandibular third molar with similar impaction

Exclusion criteria:

Poor oral hygiene Smoking and alcohol abuse Pregnant and lactating mothers

Age

From **16 years** old to **64 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Side of mandible in which mannitol is applied, is considered treatment group and Contralateral side is considered control.

Randomization (investigator's opinion)

Randomized

Randomization description

Choosing the third molar of the mandible in either side of the patient by throwing the coin. Simple randomization or unrestricted method will be used and randomization unit is Individual

Blinding (investigator's opinion)

Double blinded

Blinding description

Surgery is implemented by maxillofacial surgeon but the variables were examined by student who is blind to use or non-use of mannitol and for this reason this study is blinded both on the patient and the inspector person

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Street, Hamadan City, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6541417838741

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.UMSHA.REC.1397.672

Health conditions studied

1

Description of health condition studied

Correlation between complications associated with impacted mandibular third molar surgery and mannitol

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

1,2,4,6

Method of measurement

VAS scale

2

Description

Swelling

Timepoint

2,4,6,8

Method of measurement

Sum of 3 distances: 1- Tragus to oral commissure; 2- Lateral canthus to Mandibular angle; 3- Tragus to Pogonion

3

Description

Trismus

Timepoint

2,4,6,8

Method of measurement

Maximum opening measured between upper and lower incisors

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

8

Method of measurement

Based on planned scale

Intervention groups

1

Description

In this study, side of mandible in which mannitol is infused, is considered treatment group and would be selected randomly for each patient. Surgical removal of contralateral wisdom tooth would be performed at least 4 weeks after first surgery.

Category

Treatment - Surgery

2

Description

Contralateral side is considered control.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Hamadan University of Medical Sciences

Full name of responsible person

Omid Soltaninia

Street address

Shahid Fahmideh Street, Hamadan City, Hamadan, Iran

City

hamadan

Province

Hamadan

Postal code

65417838741

Phone

+98 81 3838 1059

Email

dentistry@umsha.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Omid Soltaninia

Street address

Hamadan university of medical Sciences, Shahid Fahmideh Street, Hamadan City, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

65417838741

Phone

+98 81 3525 0182

Email

ICT@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Omid Soltaninia

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Phone

+98 81 3838 1059

Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Omid Soltaninia

Position

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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 shared after being unidentifiable

When the data will become available and for how long

Starting the access period since 2020

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Use of data to advance other similar studies in this field

From where data/document is obtainable

contact to: omid.soltaninia@umsha.ac.ir

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

The request is checked by the compliance officer and data will be sent if the request is verified

Comments