Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 64-16 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 universiity of medical sciences

Country
Iran (Islamic Republic of)

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+98 38381058

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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

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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 commisure; 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
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Shahid Fahmideh Street, Hamadan City, Hamadan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Hamadan university of medical Sciences,Shahid Fahmideh Street, Hamadan City, Hamadan, 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
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
Asistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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