Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Intra Masseter Dexamethasone Injection on Postoperative Complications (pain, oedema and trismus) after Impacted and Semi Impacted Third Molar Surgery: A split-mouth randomized trial

Protocol summary

Study aim

The effect of Intra Masseter Dexamethasone Injection on Postoperative Complications (pain, oedema and trismus) after Impacted and Semi Impacted Third Molar Surgery

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Patients who refer to dental clinic of Medical University of Gorgan go under double side surgery with two impacted or semi-impacted wisdome teeth with same condition. Half our before surgery the one side get injected by 8 mg of dexamethasone intramasseter. For the other side nothing get injected. Time between two surgeries will be 2 week and there are two follow up in second and seventh day for each surgery due to evaluating the amount of pain, swelling and trismus.

Participants/Inclusion and exclusion criteria

1.20 to 45 years of age 2.Third mandibular molar impaction in both side 3.Kind of impaction and difficulty in both impacted tooth be even (both semi-impacted or both impacted and situation of impaction be even)\ 1.Using of interventionist medications with healing process 2.Having systemic disorders 3.Having oral and maxillofacial disease or trauma to the region 4.Having infection of pericoronitis in field of surgery 5.Manifestation of any allergic reaction, sensibility increase or immunosyncratic to the drugs

Intervention groups

Side of the mouth that surgery is performing half our before surgery is injected by intramasseter dexamethasone

Main outcome variables

Amount of Pain Swelling Trismus

General information

Reason for update

Acronym

TMDC

IRCT registration information

IRCT registration number: **IRCT20171229038128N1**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Mohamad ali Rahnama

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3255 0565

Email address

m.rahnama@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Intra Masseter Dexamethasone Injection on Postoperative Complications (pain, oedema and trismus) after Impacted and Semi Impacted Third Molar Surgery: A split-mouth randomized trial

Public title
The effect of Intra Masseter Dexamethasone Injection on Postoperative Complications after Impacted and Semi Impacted Third Molar Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
20 to 45 years of age Third mandibular molar impaction in both side Kind of impaction and difficulty in both impacted tooth be even (both semi-impacted or both impacted and situation of impaction be even)

Exclusion criteria:
Using of interventionist medications with healing process Having systemic disorders Having oral and maxillofacial disease or trauma to the region Having infection of pericoronitis in field of surgery History of allergy to lidocaine or other drugs Manifestation of any allergic reaction, sensibility increase or immunosyncratic to the drugs Definition of intervention group: Another side of the mouth that surgery is performing half our before surgery is injected by intramasseter dexamethasone. Definition of control group: Another side of the moth that surgery is performing half our before surgery is not injected by dexamethasone (all situation is the same except injection of dexamethasone)

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **19**
More than 1 sample in each individual
Number of samples in each individual: **2**
Third lower left and right mandibaular tooth

Randomization (investigator's opinion)
Randomized

Randomization description
In this type of study, randomization occurs rather than on patients, oral surgery occurs or oral areas occur. Random allocation method will be performed on a simple random type (random number list). A randomized list will be prepared by an epidemiologist who is not involved in the implementation of the interventions.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and assessing the outcomes of the study (pain, swelling and trismus) do not know the random allocation of oral areas.

Placebo
Not used

Assignment
Parallel

Other design features
This study is based on split-mouth randomized clinical trial and will be performed to evaluate the effect of intra -Masseter dexamethasone injection on the outcomes of post-operative bilateral third molars. The most important goal of this commonly used method in interventional studies Split-Mouth Design is the elimination of inter-subject variability, because each person is self-controlled. Therefore, in this type of study, randomization occurs on teeth or oral areas rather than on patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Golestan University of Medical Sciences

Street address
Dental clinic of Golestan University of Medical Science, Obverse Edalat 97 alley, Naharkhoran Blv, Gorgan,Iran

City
Gorgan

Province
Golestan

Postal code
4916953358

Approval date
2017-12-17, 1396/09/26

Ethics committee reference number
IR.GOUMS.REC.1396.231

Health conditions studied

1

Description of health condition studied
Postoperative Complications after Impacted and Semi Impacted Third Molar Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain

Timepoint
2 and 7 days after intervention
Method of measurement
VAS(Visual Analogue Scale)

2

Description
Swelling
Timepoint
2 and 7 days after intervention
Method of measurement
Swelling is measured using the reference points (lower abdomen of the lobe of the ear to the corner of the mouth and the lateral edges of the eye to the mandible corner), through a flexible ruler (a dial pad for a more accurate measurement of the curved areas) and the vignette. The caliber is made up of a combination of a dial pad and a movable veneer. The vernier ruler has two antennas, small tentacles for measuring the inside diameter and large tentacles for measuring the external diameter of the objects). Will be evaluated.

3

Description
(Trismus)
Timepoint
2 and 7 days after intervention
Method of measurement
The Trismus value will be measured by measuring the maximum distance between the two maxillary and maxillary maxillary incisors by the ventricular calcium

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:On one side of the oral surgery, dexamethasone injection of 8 mg, half an hour before surgery, and IM into the muscle of the master and will be performed by the surgeon
Category
Treatment - Surgery

2

Description
Control group:The other side of the mouth is not injected dexamethasone prior to the third molar surgery (all surgical conditions such as the oral side of the intervention except dexamethasone injection).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental school of Golestan University of Medical Sciences
Full name of responsible person
Mohamadali Rahnama
Street address
Dental clinic of Golestan University of Medical Science, Obverse Edalat 97 alley, Naharkhoran Blv, Gorgan,Iran
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Golestan University of Medical Science
Full name of responsible person
Mohamadreza Honaravar
Street address
Dental clinic of Golestan University of Medical Science, Obverse Edalat 97 alley, Naharkhoran Blv, Gorgan,Iran
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Web page address
http://goums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Golestan University of Medical Science
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

Golestan Universities of Medical Science

Full name of responsible person

Mohamadali Rahnama

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mohamadali Rahanma

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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 are available after Unrecognizable

When the data will become available and for how long

6 month after printing

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Research plan

From where data/document is obtainable

Dental school of Golestan University of Medicine Scinces

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

Submit an application to research department of dental school

Comments