

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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 wisdom 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

#### **City**

Gorgan

#### **Province**

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#### **Postal code**

4916953358

#### **Phone**

+98 17 3255 0565

#### **Email**

m.rahnama@goums.ac.ir

#### **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

#### **City**

Gorgan

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Golestan

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4916953358

#### **Phone**

+98 17 3245 1660

#### **Email**

m.rahnama@goums.ac.ir

#### **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

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Golestan Universities of Medical Science

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**Email**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Golestan Universities of Medical Science

**Full name of responsible person**

Mohamadali Rahanma

**Position**

Student

**Latest degree**

A Level or less

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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