# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jun 2026

## Investigating the effect of 2% chlorhexidine gel inside the socket on pain after surgery of the third molar of the mandible.

## Protocol summary

**Study aim**
Investigating the effect of 2% chlorhexidine gel internally on pain after mandibular impacted third molar surgery

**Design**
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 17 patients, each patient has 2 samples. Randomization using the Excel Randbetween function option

**Settings and conduct**
This study is conducted in the Faculty of Dentistry of Tehran Azad University in the Department of Oral and Maxillofacial Surgery. researcher and the patient are blinded to the study but clinician is blind. After anesthetic injection, a mucoperiosteal flap will be applied and the tooth will be loosened and removed with an elevator. Chlorhexidine 2% gel will be placed on the tested side, which is randomly selected, along with gelfoam, and gelfoam will be placed on the control side after surgery, then sutures will be applied. It is simple. All patients are given the usual care after surgery (such as painkillers). Demographic data of patients including age, gender, amount of pain while taking painkillers and the number of painkillers used are recorded. The pain level after surgery is evaluated by VAS criteria. Evaluations are performed on both the first and third days after the operation (2, 12, 24, 72 hours after the operation,).

**Participants/Inclusion and exclusion criteria**
People who are fully satisfied after explaining the procedures and purpose of the research and do not have any specific systemic problems and are 18-25 years old and need bilateral lower third molar surgery.

**Intervention groups**
Intervention group: Placing 2% chlorhexidine gel in the socket of one side (right or left) of the impacted impacted third molar, control group: Placing placebo on the other side.

**Main outcome variables**
Pain at 2,12,24,72 hours after surgery on the intervention and control side based on VAS criteria.The VAS is a score from 1-10 , (1: no pain,10: unbearable pain).

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230721058874N1**
Registration date: **2023-08-06, 1402/05/15**
Registration timing: **prospective**

Last update: **2023-08-06, 1402/05/15**
Update count: **0**

**Registration date**
2023-08-06, 1402/05/15

**Registrant information**

**Name**
Alireza Fathi

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-10-01, 1402/07/09

**Expected recruitment end date**
2023-11-30, 1402/09/09

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Investigating the effect of 2% chlorhexidine gel inside the socket on pain after surgery of the third molar of the mandible.

**Public title**
Investigating the effect of chlorhexidine on pain after extraction of lower wisdom teeth

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
People who are 18-25 years old. Needs bilateral extraction of mandibular impacted third molar with difficulty level of 7-10 according to Pederson criteria. The mucus on the tooth should be healthy.

**Exclusion criteria:**
People with a history of systemic diseases, pregnancy, infection in the area, use of anti-coagulant drugs, presence of painful conditions such as teeth needing root canal treatment, neurological diseases and use of nerve drugs, having a history of allergies. People who do not give consent after explaining the steps and purpose of the research.

**Age**
From **18 years** old to **25 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **17**
More than 1 sample in each individual
Number of samples in each individual: **2**
The right mandibular third molar and the left mandibular third molar

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In each patient, in a simple random manner (by Excel software using the Randbetween function option), the impacted molar tooth on one side is considered as the case group and the other side as the control.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Before starting the surgery, the research procedures were explained to the patient, and a consent form was obtained from him or her. On the day of the surgery, the resident (clinician who is not blinded to the study) at Tehran Azad Dental School after surgery and tooth extraction on the Intervention side, which is chosen by simple random before the surgery, he puts chlorhexidine gel and placebo on the control side and writes the information in a form and puts it in a closed envelope and hands it to the researcher. The patient and the researcher, who is the outcome evaluator, are blind, and after evaluating the outcome (which is the evaluation of the patient's pain in each side), he opens the information form and compares and analyzes the data.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Faculty of Dentistry of Tehran Azad University

**Street address**
south Sohrevardi east Abrar alley No 5

**City**
Tehran

**Province**
Tehran

**Postal code**
1566635111

**Approval date**
2023-06-14, 1402/03/24

**Ethics committee reference number**
IR.IAU.DENTAL.REC.1402.029

## Health conditions studied

### 1

**Description of health condition studied**
Dry socket

**ICD-10 code**
M27.3

**ICD-10 code description**
Alveolitis of jaws

### 2

**Description of health condition studied**
Impacted teeth

**ICD-10 code**
K01.1

**ICD-10 code description**
Impacted teeth

## Primary outcomes

### 1

**Description**

Pain after impacted mandibular third molar surgery based on Visual Analogue Scale

**Timepoint**

Pain assessment after 2, 12, 24, 72 hours after surgery, respectively

**Method of measurement**

Visual Analogue Scale Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: One patient's jaw, which was randomly selected, and after surgery, chlorhexidine gluconate 2% gel Morva Sept, made in Iran, in the amount of 1 ml, was applied to resorable Roeko Gelat Amp gelofoam, made in Germany, and placed in the socket.

**Category**

Prevention

### 2

**Description**

Control group: Roeko Gelat Amp absorbable gel foam made in Germany is placed in the patient's toothless socket after surgery.

**Category**

Prevention

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Faculty of Dentistry, Azad University of Medical Sciences, Tehran

**Full name of responsible person**

Eshagh Lasemi

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No 9 . Ninth Neyestan . Pasdaran

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

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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**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Eshagh Lasemi

**Position**

Associate professo

**Latest degree**

Specialist

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

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

**Title and more details about the data/document**
The research process and the main results of the research and data about the patients are accessible

**When the data will become available and for how long**
1 year after the results are published

**To whom data/document is available**
Researchers working in academic and scientific institutions and people working in industry can apply for them

**Under which criteria data/document could be used**
If the patient is fully satisfied and if it is aimed at improving the patient's condition and preventing the patient's problems, the documents can be used and available

**From where data/document is obtainable**
You can contact this email for correspondence and exchange of views arya.fathi77.af@gmail.com

**What processes are involved for a request to access data/document**
It must be for research or treatment

**Comments**