

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 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 5068

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arya.fathi77.af@gmail.com

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 resorbable Roeko Gelat Amp gelfoam, 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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1946853314

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Email

arya.fathi77@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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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 professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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