

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Delayed Infection in Envelope and Three-Corner Flaps in Impact Mandibular Third Molar Surgery, a Prospective Study

Protocol summary

Study aim

Comparison of delay infection in envelope and three-corner flaps in impact mandibular third molar surgery in Tehran Azad Dental University and Shahid Beheshti University and Behfar Clinic and Ghazi Tabatabaee Clinic.

Design

The clinical trial study contains two parallel groups which are double blind randomized by using a four-segment block.

Settings and conduct

Subjects who have similar impacted teeth bilaterally will be undergo surgeries for removal them. Randomly, three corner flap will be used in a side and an envelope flap will be applied to another side. The prevalence of the delayed infection will be estimated in each side.

Participants/Inclusion and exclusion criteria

Including Criteria: People Having ASA1 Systemic Condition. Subjects are candidate for both Mandibular Impacted Third Molar Surgery. Both Impacted Teeth Must be In the Same Pell and Gregory Classification. Subjects' age Must Be Between 18 to 30 Years. Exclusion Criteria: Patients with decayed second mandibular tooth which need a root canal therapy. Smoker patients. Patients who have pathologic lesion around impacted wisdom tooth. Patients with incapability of mouth opening over 35 millimeters. Patients with poor oral hygiene. Patients who have got mandible trauma. Patients who are not capable to come over for a follow-up session. Patients who do not use antibiotics and antiseptics by regular given order.

Intervention groups

The three corner flap sides the envelope flap sides

Main outcome variables

Pain; swelling; redness; pus discharge 2 to 6 weeks after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210920052527N1**

Registration date: **2021-10-20, 1400/07/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-20, 1400/07/28**

Update count: **0**

Registration date

2021-10-20, 1400/07/28

Registrant information

Name

Mohammad Reza Soleimanpour Boroujeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4570

Email address

m.soleimanpour@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Delayed Infection in Envelope and Three-Corner Flaps in Impact Mandibular Third Molar Surgery, a Prospective Study

Public title

Delayed Infection in Two Types of Wisdom Tooth Surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People Having ASA1 Systemic Condition People Candidate for Both Mandibular Impacted Third Molar Surgery Both Impacted Tooth Must be In Same Pell and Gregory Classification Patient Age Must Be Between 18 to 30 Years.

Exclusion criteria:

Patients with decayed second mandibular tooth which needs a root canal therapy. Smoker patients. Patients who have got a pathologic lesion around impacted wisdom tooth. Patients with incapability of mouth opening over 35 millimeters. Patients with poor oral hygiene. Patients who have got mandible trauma. Patients who are not capable to come over for a follow-up session. Patients who do not use antibiotics and antiseptics by regular given order.

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **202**

Randomization (investigator's opinion)

Randomized

Randomization description

Every 4 indicated patients who are referred to dental departments of Shahid Beheshti University, Tehran Azad University, Behfar clinic and Ghazi Tabatabaee for wisdom tooth removal surgery are planned to include in quadruple blocks. This block is actually a table of 2x2 which its columns title is name of flap and its rows title is the side of surgery. This blocks include side and type of the first surgery which was extracted from the table in line before: Right side and Three-corner flap, right side and envelope flap, left side and three-corner flap, and left side and envelope flap. These data would be given in 4 sealed pockets to the surgeon and surgeon would pick one of them. After that, surgeon will operate patient according to the selected data. Every 4 patient must undergo surgery according to one of these pockets. The other flap on the other side would be operated according to the picked pockets.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and analyzer will not know about the inside of the pocket given to the surgeon. (However patients would be aware of the study. Also patients would find out which tooth undergoes operation.) Also the surgeon would not be informed about which sealed pockets would contain

what information. The surgeon will pick up one of the sealed pockets randomly.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran Azad University of Medical Sciences.

Street address

No. 9, Arghavan Alley, North Behzad Boulevard, Second Abghari Street, Saadat Abad

City

Tehran

Province

Tehran

Postal code

1998666898

Approval date

2021-08-04, 1400/05/13

Ethics committee reference number

IR.IAU.DENTAL.REC.1400.050

Health conditions studied**1****Description of health condition studied**

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ICD-10 code

ICD-10 code description

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Primary outcomes**1****Description**

Delayed infection after surgery with pain, redness, swelling, pus discharge and restriction of maximum mouth opening symptoms.

Timepoint

2 weeks after surgery, 4 weeks and 6 weeks.

Method of measurement

Clinical evaluation for detection of infection (redness, pain, swelling, pus discharge and restriction of maximum mouth opening)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who undergo third mandibular molar impacted extraction surgery with a three-corner flap at first. After surgery, the flap will suture with a 000 silk sew thread. Second surgery will operate immediately after first surgery. In second surgery, the flap will change. this wound will be suture with a 000 silk sew thread. Patients have to use antiseptics and antibiotics according to the protocols.

Category

Treatment - Surgery

2

Description

Intervention group: Patients who undergo third mandibular molar impacted extraction surgery with a envelope flap at first. After surgery, the flap will suture with a 000 silk sew thread. Second surgery will operate immediately after first surgery. In second surgery, the flap will change. this wound will be suture with a 000 silk sew thread. Patients have to use antiseptics and antibiotics according to the protocols.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery Department of Shahid Beheshti University

Full name of responsible person

Parisa Moradi

Street address

Dental School, Daneshjou Bolevard, Velenjak

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2

Recruitment center

Name of recruitment center

Behfar Clinic

Full name of responsible person

Parisa Moradi

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Damavand street

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3

Recruitment center

Name of recruitment center

Ghazi Tabatabaee

Full name of responsible person

Parisa Moradi

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Farrkhi Yazdi square, Pasdaran Avenue

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Recruitment center

Name of recruitment center

Dental Department, Azad Tehran University of Medical Sciences

Full name of responsible person

Parisa Moradi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Mohammadreza Soleimanpour Borujeni

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9th Neyestan, Pasaran avenue

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Phone

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m.soleimanpour@iautmu.ac.ir

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

Parisa Moradi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Tabrizi Miyandoab

Position

Associate Professor

Latest degree

Subspecialist

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Parisa Moradi

Position

student

Latest degree

Medical doctor

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

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

The data will be published through the research commits

When the data will become available and for how long

After finishing the accumulation of the data

To whom data/document is available

Dental students , researchers

Under which criteria data/document could be used

With permission from the research commits

From where data/document is obtainable

The research commits

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

The request from the research committees.

Comments