Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 21 2256 4570

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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 2×2 which its columns title is name of flap and its raws 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 Bolevard, Second Abghari Street, Saadat Abad
City
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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
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3

Recruitment center
Name of recruitment center
Ghazi Tabatabaee
Full name of responsible person
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4

Recruitment center
Name of recruitment center
Dental Department, Azad Tehran University of Medical Sciences
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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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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

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Full name of responsible person
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Position
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Subspecialist

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Dentistry

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Person responsible for updating data

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Name of organization / entity
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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