Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Evaluation of Two Different Envelope Flap Designs on Postoperative Outcomes in the Surgical Removal of Bilateral Impacted Mandibular Third Molar

Protocol summary

Study aim

Since Envelope Flap in most of the Impacted Wisdom teeth Surgery is the Choice of Many Surgeons to Reduce Trauma and Reduce Suturs and because Many Studies have Compared the Effects of Envelop flap and Triangular flap, There is no Comparative study between the Short and Common Envelope flaps. This Study was Conducted to Compare the Effect short Envelope flap and common Envelope flap on post-operative complications of Bilateral Impacted Mandibular third Molar Surgery .

Design

This Research is based on a Single Blind and a Randomized Clinical Trial

Settings and conduct

The Subjects were Aelected from Patients referring to Ahvaz Jundishapur Dentistry Department in 1398-99

Participants/Inclusion and exclusion criteria

All patients were Indications of bilateral Impacted Mandibular third molar Surgery . Patients were not included in the study if they were subject to the following conditions. 1. Acute or chronic periapical Inflammation 2. Systemic Problems or use of Srugs that affect Wound Healing 3. Pregnancy 4. Pericoronitis 5. teeth that had a Major Difference in the Degree of Impaction either Side of the Patient. If the Patient is not Followed up for Re-examination, the patient is Excluded from the Study

Intervention groups

The Control Group (the Common Envelope Flap) and the Case Group (Short Envelop flap) are Examined in one Patient and at the two sides of Mandible. Two teeth Extracted with an Interval of 14 Days, which Patients are Randomly Assigned to two groups

Main outcome variables

Pain was Determined using Visual Analog Scal and Facial Swelling was evaluated using a Tape Measuring method. Trismus was Determined by Measuring Maximum Interincisal Opening

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181117041685N1**
Registration date: **2020-03-14, 1398/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-14, 1398/12/24**
Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Arman Babadi

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

2019-12-29, 1398/10/08

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative Evaluation of Two Different Envelope Flap Designs on Postoperative Outcomes in the Surgical Removal of Bilateral Impacted Mandibular Third Molar

Public title
Effect of Flap Designs on Postoperative Outcomes in the Surgical Removal of Impacted Mandibular Third Molar

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patient with Bilateral Impacted Mandibular Third Molar All of third molars based on Pell and Gregory were in the A, B, C group and Class 1 or 2 And angle of impaction was mesioangular, vertical, horizontal, or distoangular Patients Age Were 16-35 years old
Exclusion criteria:
Presence of Acute or Chronic Periapical inflammation Presence of Systemic Disease Taking Medications that Affect Wound Healing Pregnancy Presence of Pericoronitis Teeth that Have a Major Difference in the Degree of Impaction on the Sides of a Patient Tooth that Have a Very Deep Impaction

Age
From **16 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **66**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each patient has 2 impacted wisdom teeth

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization

Blinding (investigator's opinion)
Single blinded

Blinding description
just Participants are unaware of the allocation of study groups

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Dental Faculty of Jondishapour university
Street address
Esfand ave Golestan
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Ahvaz
Province
Khouzestan
Postal code
5326841265

Approval date
2019-12-28, 1398/10/07

Ethics committee reference number
it.ajums.rec.1398.705

Health conditions studied

1

Description of health condition studied
Bilateral impacted mandibular third molar

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Postoperative Pain

Timepoint
The Second and the Seventh Days After Surgery

Method of measurement
Visual Analog Scale

2

Description
maximum Mouth Opening after Surgery

Timepoint
Before Surgery ,The Second and the Seventh Days After Surgery

Method of measurement
Measuring the Distance Between the Upper and Lower Anterior Teeth with the Ruler

3

Description
Occurance of Dry Socket After Surgery

Timepoint
The Second and the Seventh Days after Surgery

Method of measurement
occurrence of Dry Socket with the Onset of Severe Pain from the Second or Third day and Clinical Symptoms of the Socket will Diagnose

Secondary outcomes

1

Description
The Amount of Swelling
Timepoint
Before Surgery ,The Second and the Seventh Days After Surgery
Method of measurement
Postoperative Swelling was Measured as an Observational Evaluation. The Distance Between Tragus - Alar of Nose (A), the Distance between the Tragus - Oral Commissure (B) and Tragus - Soft Tissue of Pogonion (c) is as Follows: Patient is Straight and Sit at a 90 Degree and the Jaw is at Rest

2

Description
Maximum Mouth Opening
Timepoint
Before Surgery ,The Second and the Seventh Days after Surgery
Method of measurement
Measuring the Distance Between the Upper and Lower Anterior Teeth with the Ruler

3

Description
Postoperative Pain
Timepoint
The Second and the Seventh Days after Surgery
Method of measurement
Visual Analog Scale

4

Description
Incidence of Dry Socket
Timepoint
The Second and the Seventh Day after Surgery
Method of measurement
Occurrence of a Dry Socket with the Onset of Severe Pain from the Second or Third Day and Clinical Symptoms of the Socket will diagnose

Intervention groups

1

Description
Intervention group: short envelope flap contains sulcular incision from mesial of mandibular second molar without involving interdental papilla , to disto buccal angel of second molar and extending the incision toward the anterior rim of ramus
Category
Treatment - Surgery

2

Description
Control group: commen envelope flap contains sulcular incision from mesial of mandibular first molar without involving interdental papilla , to disto buccal angel of second molar and extending the incision toward the anterior rim of ramus
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Jondishapour Dental faculty of Ahvaz
Full name of responsible person
Kazem Khiabani Savjebalaghchi
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Sponsors / Funding sources

1

Sponsor
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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
Ahvaz University of Medical Sciences
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

Ahvaz University of Medical Sciences

Full name of responsible person

Kazem Aavjebalaghchi Khiabani

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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