

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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 Aecteded 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3337 9113

##### Email address

ad232223@gmail.com

##### 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

##### City

Ahvaz

##### Province

Khuzestan

##### 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

##### Street address

Dey Ave., Goldstan., Jondishapour dental facility

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##### Phone

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Kazem Savjebalaghchi Khiabani

##### Street address

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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**

Oral and Maxillofacial Surgery

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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