Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of post-op complications of two different flap designs for impacted third mandibular molar surgery

Protocol summary

Study aim
Determining the flap design (between envelope flap and comma flap) which has the least post-op complications such as : pain, edema, trismus, wound dehiscence, any alteration in lingual nerver sensation and alveolar osteitis

Design
Clinical trial with control group, single blinded, split mouth, randomized, on 25 patients (50 patients overall), for randomizing coin flipping is used.

Settings and conduct
On patients whom selected in oral and maxillofacial section of Islamic Azad university of Tabriz two flaps will be designed. comma flap: starting from a point at the depth of stretched vestibular reflection, posterior to the 2nd molar distal aspect, the incision is made anteriorly, to a point below the second molar, from where it smoothly curved up to the gingival crest at the 2nd molar distobuccal line angle. it is continued as a crevicular incision around the distal aspect of the 2nd molar. envelope flap: an incision from external oblique ridge of mandible to 2nd molar middistobuccal line angle will be made. additionally a sulcular incision on 2nd molar distofacial line angle will be made and continued up to 1st molar mesiofacial line angle.

Participants/Inclusion and exclusion criteria
Among patients who admitted in oral and maxillofacial section of Islamic Azad university of Tabriz, faculty of dentistry; 25 patients will be chosen who have bilateral and symmetrical impacted mandibular third molar. based on Pell and Gregory classification, class1,2, A, B tooth will be included. patients with any systemic disease or underlying disease and acute periodontal diseases and those with tooth on class 3,C Pell and Gregory classification will be excluded.

Intervention groups
Comma flap for case group (group A) and envelope flap for control group (group B) will be used

Main outcome variables
Pain; edema; trismus; flap design; wound dehiscence; alveolar osteitis; alteration in lingual nerve sensation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230202057309N1**
Registration date: **2023-03-16, 1401/12/25**
Registration timing: **prospective**

Last update: **2023-03-16, 1401/12/25**
Update count: **0**

Registration date
2023-03-16, 1401/12/25

Registrant information

Name
Farid Ghasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3651 6267

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-08-22, 1402/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of post-op complications of two different flap designs for impacted third mandibular molar surgery

Public title
Evaluation of post-op complications of envelope flap and comma flap for impacted third molar

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have bilateral and symmetrical impacted mandibular third molar Patients who have class 1,2,A,B impacted mandibular third molar, based on Pell and Gregory classification Patients who have not any systemic or underlying disease Patients whom impacted mandibular third molar has no symptom such as pain, edema and trismus Patients whom root of impacted mandibular third molar has developed more than one-third Patients who have no acute periodontal disease

Exclusion criteria:

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **25**
More than 1 sample in each individual
Number of samples in each individual: **2**
Patients with bilateral and symmetrically impacted mandibular third molar teeth.

Randomization (investigator's opinion)
Randomized

Randomization description
The impacted tooth will assigned into two lingually based comma flap(group A) and envelope flap(group B), by flipping a coin. For choosing which quadrant to start with, also there will be a coin flipping.

Blinding (investigator's opinion)
Single blinded

Blinding description
It will be explained to the patients that one distinct flap design will be used for every impacted mandibular third molar on each quadrant. But they will be not informed, which one of those two flap designs will be used on which quadrant.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University Tabriz branch

Street address
Tabriz Islamic Azad Medical University, Jadde Basmanj, East Azerbaijan Province, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5159115705

Approval date
2023-03-07, 1401/12/16

Ethics committee reference number
IR.IAU.TABRIZ.REC.1401.332

Health conditions studied

1

Description of health condition studied
Post-op complications comparison of two comma and envelope flap design in impacted third mandibualr surgery

ICD-10 code
K01.1

ICD-10 code description
Impacted teeth

Primary outcomes

1

Description
Pain: post-operative pain will be measured by Visual Analog Scale. In this scale, the patients will be asked to show the intensity of the pain which is experienced by choosing a number(between 0-10) on a horizontal line. Pain in this descriptive scale is categorized to 6 levels: 0= no pain, 1-3= mild pain, 4-5= moderate pain, 6-7= painful, 7-8= sever pain and 10= unbearable pain. The paitients will be asked to report the pain score on its worst severity time on a day.

Timepoint
Will be measured on the first, third and seventh post-operative day.

Method of measurement
Visual Analog Scale

2

Description
Edema: the severity of post-operative edema will be measured by the pre-operative difference between the two fixed mandibular angle and lip commissure points on the patients' face and the post-operative one.

Timepoint
Will be measured on the first, third and seventh post-operative day.
Method of measurement
The pre-operative difference between the two fixed mandibular angle and lip commissure points on the patients' face and the post-operative one (in milimeter)

3

Description
Trismus: will be measured post-operatively. for this purpose the inter-incisal distance will be measured. if the distance is less than 25 milimiter, the presence of trismus will be considered.
Timepoint
Will be measured on the first, third and seventh post-operative day.
Method of measurement
the maximum inter-incisal distance (in milimeter).

4

Description
Wound dehiscence: to a dehiscence more than 1.5 centimeter square, number 3, less than 1 centimeter square, number 2 and less than 0.5 centimeter square, number 1 will be assigned. in case of no dehiscence number 0 will be considered.
Timepoint
Will be measured on the first, third and seventh post-operative day.
Method of measurement
the amount of post-operative wound dehiscence (in centimeter square).

5

Description
Alveolar osteitis: will be considered post-operative pain in or around the socket of the extracted impacted tooth or partial/total loss of the blood clot in the socket (yes or no).
Timepoint
Will be measured on the first, third and seventh post-operative day.
Method of measurement
post-operative pain in or around the socket of the extracted impacted tooth or partial/total loss of the blood clot in the socket (yes or no).

6

Description
Lingual nerve paraesthesia: in order to evaluate any post-operative injury or paraesthesia to lingual nerve, changes on the lateral surface of tounge will be investigated.
Timepoint
Will be measured on the first, third and seventh post-operative day.
Method of measurement
any post-operative injury,paraesthesia or aneasthesia on the lateral surface of tounge (any changes in sensation , yes and no changes in sensation, no).

Secondary outcomes

empty

Intervention groups

1

Description
Control group:The impacted tooth will assigned into two lingually based comma flap(group A) and envelope flap(group B), by flipping a coin. For choosing which quadrant to start with, also there will be a coin flipping.
Category
Treatment - Surgery

2

Description
Intervention group: The impacted tooth will assigned into two lingually based comma flap(group A) and envelope flap(group B), by flipping a coin. For choosing which quadrant to start with, also there will be a coin flipping.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
oral and maxillofacial section of Islamic Azad university of Tabriz, faculty of dentistry
Full name of responsible person
Dr.Yousef Kananizadeh
Street address
Tabriz Islamic Azad Medical University, Jadde Basmanj, East Azerbaijan Province, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr.Yousef Kananizadeh

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Tabriz Islamic Azad Medical University, Jadde Basmanj, East Azerbaijan Province, Iran
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Phone
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Email
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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
Farid Ghasemi
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
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Full name of responsible person
Farid Ghasemi
Position
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Latest degree
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Person responsible for updating data

Contact

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Farid Ghasemi
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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

all of the patients' data except their name and contact information, will be shared.

When the data will become available and for how long

6 months after publishing of the results.

To whom data/document is available

People who practice in medical field, like medical doctors and dentists.

Under which criteria data/document could be used

Access permit to data will only be allowed in case of evaluating the exactitude of the study and using its benefits for treating patients.

From where data/document is obtainable

1) Farid Ghasemi f.gh1372@gmail.com (+98)9134728100 Skype: f.gh1372 2) Yousef Kananizadeh dr.kananizadehy@gmail.com

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

Please contact with one of the two person mentioned, by e-mail or phone. after evaluating the request, in 2 weeks the data will be sent.

Comments