

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of releasing (relaxing) incision on the postoperative complication of mandibular third molar surgery

Protocol summary

Summary

The aim of this study is to evaluate the effect of releasing incision after mandibular third molar surgery. In this clinical trial (Single blind), 20 patients according to inclusion criteria (age range 15-35 years, etc.) and exclusion (smoking, etc.) are selected. In each patient a triangular flap (conventional triangular or bayonet flap) in one side and an envelope flap on the other side is used. The side of the surgery to supply the flap is selected by random table and examiner is unaware of it. The time interval between the two surgeries is at least one month. Envelope flap incision is started from anterior edge of mandibular ramus and 1 cm distally from second molar then is extended from buccal gingival sulcus of second molar to mesiobuccal of second premolar. Triangular flap incision is started from anterior edge of mandibular ramus and 1 cm distally from second molar then it is extended in buccal gingival sulcus to mesiobuccal of second molar and finally connected to the releasing incision in mesiobuccal region with at least 1 cm length extension to buccal vestibular. Primary outcome: complication after surgery and secondary outcomes: Pain(measurement times:Daily up to a month after surgery), swelling, Trismus, Ecchymosis (measurement times: 3, 7, 14 days preoperatively and finally 1 month postoperatively) and duration of surgery (Since the beginning of surgery to the end of the last stitch)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506191760N42**

Registration date: **2015-07-06, 1394/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-06, 1394/04/15

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health
Research Center, Babol University of Medical
Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of releasing (relaxing) incision on the
postoperative complication of mandibular third molar
surgery

Public title

The effect of releasing (relaxing) incision on the

postoperative complication of mandibular third molar surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age range 15-35 years; Mandibular third molar teeth surgery candidates with Pell & Gregory and classified in categories 1 and 2 -A, B Exclusion criteria: Smoking; Taking certain medications such as Corticosteroids or immunosuppressive drugs bisphosphonates; Illnesses such as diabetes, anemia and other debilitating diseases of the immune system; Haemorrhagic disease or taking anticoagulants; Background radiation in head and neck; pericoronitis or any pathological lesions associated with third molars is not growing; Significant injury periosteal flap envelope in

Age
From **15 years** old to **35 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
This study is Single blind. All patients underwent surgery by a fall, and assessments before and after surgery by colleagues(provided by flaps on both sides of the patient is not aware of) is done. In order to provide the flap, the choice of the surgery is done by random table and examine the person is unaware of it.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical sciences

Street address

Babol University of Medical Sciences, Ganjafroz Avenu

City

Babol

Postal code

Approval date

2014-11-17, 1393/08/26

Ethics committee reference number

4834

Health conditions studied

1

Description of health condition studied

Impacted teeth

ICD-10 code

K01

ICD-10 code description

Embedded and impacted teeth

Primary outcomes

1

Description

Complications After Surgery

Timepoint

Daily up to a month after surgery

Method of measurement

Clinical

Secondary outcomes

1

Description

Pain Index

Timepoint

Daily up to a month after surgery

Method of measurement

Visual Analogue Scale

2

Description

Inflation

Timepoint

On the third, seventh, fourteenth, and one month after surgery

Method of measurement

Clinical

3

Description

The Lockjaw

Timepoint

On the third, seventh, fourteenth, and one month after surgery

Method of measurement

Clinical

4

Description

Ecchymosis

Timepoint

On the third, seventh, fourteenth, and one month after surgery
Method of measurement
Clinical

5

Description

Duration of surgery

Timepoint

Since the start of operation by the end of the last stitch

Method of measurement

Clinical

Intervention groups

1

Description

Intervention groups: : triangular flap incision is started from anterior edge of mandibular ramus and 1 cm distally from second molar then it is extended in buccal gingival sulcus to mesiobuccal of 2nd molar and finally connected to the releasing incision in mesiobuccal region with at least 1 cm length extension to buccal vestibular. After reflecting full thickness flap, bone removal (Osteotomy) and if sectioning of third molar (Odontomy) is required, done by using surgery bur. finally, after full restoration of homeostasis the flap is re-positioned to primary site and sutured.

Category

Treatment - Surgery

2

Description

Control groups: Envelope flap incision is started from anterior edge of mandibular ramus and 1 cm distally from second molar then is extended from buccal gingival sulcus of second molar to mesiobuccal of second premolar.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental colleges of Babol

Full name of responsible person

Sara Ali Asghari

Street address

Dental colleges of Babol, Babol University of Medical Sciences, Ganjafroz Avenue

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Babol University of Medical Sciences, Ganjafroz Avenue

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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

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dental colleges of Babol

Full name of responsible person

Sara Ali Asghari

Position

Dental students

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dental colleges of Babol

Full name of responsible person

Dr. Ramin Frooghi

Position

Oral and Maxillofacial Surgery

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Nargess Gholizadeh Pasha

Position

MSc

Other areas of specialty/work