Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of newly Presented Suturing technique with Conventional Suturing on Severity of Complications Following Mandibular fully Impacted third molar Surgery

Protocol summary

Study aim

The innovative suture technique with conventional suture during mandibular fully impacted third molar surgery on the severity of postoperative complications will compare

Design

Controlled clinical trial with a parallel group, double blinded, randomized with statistical software using blocks of six

Settings and conduct

This study carried out in department of Surgery, Faculty of Dentistry, Semnan University of Medical Sciences The suture pattern will be selected randomly in the first surgery and will not be shown to the surgeon prior to the start of suturing and finishing the surgical procedure. The patient and measurer will be blind about the type of suture

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged between 20 and 30 Both-sided and symmetrical impaction of mandibular third molar tooth that are classified in the same class by Pell & Gregory Meeting ASA1 systemic conditions Collaborative patients with frequent visits for follow-up Patients without periodontal disease The exclusion criteria of the study include: Pathologic lesion in the impacted tooth Difference in follicle size around the crown of each person's sides Taking steroids, drugs, alcohol, contraceptives Pregnancy and lactation History of delayed wound healing Failure to complete follow-up sessions

Intervention groups

In the control side simple loop suture.In the case side, first the thread will be twisted around the needle holder in clockwise direction A)Then, with the aid of the needle holder the middle of the loose thread is taken and passed around the needle holder through the twisted thread to form a loop B)The needle holder is passed through the loop into the free end of the thread and pulled to complete the knot

Main outcome variables

Pain؛ maximal؛ oral opening rate؛ facial swelling؛ the 7th tooth distal pocket depth؛ clinical attachment loss in 7th tooth distal؛ dry sockt؛ dehiscence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181021041404N1**
Registration date: **2018-11-14, 1397/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-14, 1397/08/23**
Update count: **0**

Registration date

2018-11-14, 1397/08/23

Registrant information

Name

MohammadHosein Mansourian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-07, 1397/08/16

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of newly Presented Suturing technique with Conventional Suturing on Severity of Complications Following Mandibular fully Impacted third molar Surgery

Public title

Comparison of Innovative Suture with Conventional Suture on Severity of Complications Following Mandibular fully Impacted third molar Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both-sided and symmetrical impaction of mandibular third molar tooth that are classified in the same class by Pell & Gregory Meeting ASA1 systemic conditions Non-smokers patients Collaborative patients with frequent visits for follow up Patients without periodontal disease patients with proper oral hygiene patients aged between 20 and 30

Exclusion criteria:

Pathologic lesion in the impacted tooth Difference in follicle size around the crown of each person's sides Surgical time exceeding 25 minutes More than 5 minutes of surgical difference on both sides Taking steroids, drugs, alcohol, contraceptives Pregnancy and lactation History of delayed wound healing Failure to complete follow up sessions

Age

From **20 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Right and left mandibular fully impacted third molar

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize, patients are divided into two groups using the blocks of six that made by statistical software: In the first group, the first surgery is on the lower right jaw, and in the second group, the first surgery is performed on the lower left jaw. All surgeries will be performed by an oral and maxillofacial surgeon and in one room with an assistant. The suture pattern will be selected randomly in the first surgery and will not be shown to the surgeon prior to the start of suturing and finishing the surgical procedure.

Blinding (investigator's opinion)

Double blinded

Blinding description

The suture pattern will not be shown to the surgeon(main researcher) prior to the start of suturing and finishing the surgical procedure. The patient and measurer will be blind about the type of suture.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Vice chancellor for research, Setad building, Basij Blvd

City

Semnan

Province

Semnan

Postal code

35198-99951

Approval date

2018-10-17, 1397/07/25

Ethics committee reference number

IR.SEMUMS.REC.1397.157

Health conditions studied

1

Description of health condition studied

Mandibular fully impacted third molar surgery

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

2

Description of health condition studied

Postoperative facial swelling after mandibular fully impacted third molar surgery

ICD-10 code

R22.9

ICD-10 code description
Localized swelling, mass and lump, unspecified

3

Description of health condition studied
Trismus after mandibular fully impacted third molar surgery
ICD-10 code
S03.4
ICD-10 code description
Sprain of jaw

4

Description of health condition studied
Dehiscence after mandibular fully impacted third molar surgery
ICD-10 code
T81.31
ICD-10 code description
Disruption of external operation (surgical) wound, not elsewhere classified

5

Description of health condition studied
Dry socket after mandibular fully impacted third molar surgery
ICD-10 code
K10.3
ICD-10 code description
Alveolitis of jaws

Primary outcomes

1

Description
pain
Timepoint
Before starting surgery, it is assessed that there is no pain at the surgical site.pain of the patient 12 hours after surgery and on days 7, 1, 2, 3, 4, 5, 6 after surgery will be measured.
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Swelling
Timepoint
Before starting surgery, 24 hours after surgery and the days 3rd and 7th after surgery
Method of measurement
Facial width will be measured by ticking three facial distances on a thread and then measuring it by a ruler. Horizontal: The distance between the corners of the lip to the attachment of the ear lobe on same side and the thread is subject to the cheeks. Vertical: The distance between the outer eye cantos and the mandibular angle of the same side and the thread is subject to the cheeks. Oblique: The distance from the corners of the lip and the mandibular angle of the same side and the thread is subject to the possible facial swelling (post-operative swelling)

2

Description
Maximal oral opening rate
Timepoint
Before starting surgery, 24 hours after surgery and the days 3rd and 7th after surgery
Method of measurement
It will be calculated by measuring the distance between the central margin of the upper jaw and the central edge of the lower jaw (or left in the absence of the right central) by the digital caliper (Mitutoyo, Illinois, USA).

3

Description
Dry socket
Timepoint
24 hours after surgery and the days 3rd and 7th after surgery
Method of measurement
Blums criteria

4

Description
Dehiscence
Timepoint
24 hours after surgery and the days 3rd and 7th after surgery
Method of measurement
The self-opening of sutures without patient’s intervention that define with observations

5

Description
Clinical attachment loss in 7th tooth distal
Timepoint
Before starting surgery, six months after surgery
Method of measurement
The distance between CEJ and the pocket bottom will be measured by william probe (Juya Instruments PVT, Tehran, Iran)

6

Description
The 7th tooth distal pocket depth
Timepoint
Before starting surgery, six months after surgery
Method of measurement
The distance between the gingival margin and pocket bottom will be measured by the william probe (Juya Instruments PVT, Tehran, Iran)

Intervention groups

1

Description
Intervention group:first the thread will be twisted around the needle holder in clockwise direction A)Then, with the aid of the needle holder the middle of the loose thread is taken and passed around the needle holder through the twisted thread to form a loop B)The needle holder is passed through the loop into the free end of the thread and pulled to complete the knot C)same process is repeated for the second time

Category
Treatment - Surgery

2

Description
Control group:A suture will be made on the releasing incision and two sutures will be implemented on 7th tooth distal and mesial papillae with a common knot.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Semnan Dental School

Full name of responsible person
Mohammad Esmaeelnejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research center of Semnan Dental School

Full name of responsible person
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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
Research center of Semnan Dental School

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
Semnan University of Medical Sciences

Full name of responsible person
Mohammad Esmaeelnejad

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Oral and maxillofacial surgery

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Position

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Latest degree

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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