Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of Silk Sutures and Tissue Adhesives for wound closure of Impacted Third Molar Teeth surgery: Clinical and Histological Evaluation

Protocol summary

Study aim

Comparing effect of tissue adhesive and silk suture for closure of surgical wound after removal of impacted mandibulae third molar:clinical and histologic

Design

Two arm parallel group randomised trial without blinding and Simple randomizatio by Random number table and target sample size:40

Settings and conduct

People with two impacted mandibular third molar will be chosen in dental school.After simple randomization as even and odd,In the first surgery, after the removal of the third molar tooth,the flap of right side will be closed in the evens by suturing and in odds by tissue adhesive and After a week, a biopsy will be performed from surgery site.After more than 2 weeks,The third molar of the opposite side will be removed and Sutures will be used for close the flaps of odds and tissue adhesive will be used to close the flaps of evens and After a week, a biopsy will be performed from surgery site.Sutures as control group will be compared with tissue adhesive as intervention group.

Participants/Inclusion and exclusion criteria

Inclusion critria: All subjects of 18 years and above with mesio-angularly impacted mandibular third molar Subjects whitout known systemic disease such as bleeding dyscrasia and immunosuppression Subjects not allergic to the drugs or anaesthetic agents in the surgical protocol Subjects with good oral hygiene Subjects who are non-smokers Exclusion criteria: Subject with severe caries of the second molar teeth Subject between the age of 18 & 25 who have vertical class 1 and level A pell & gregory classification impaction in third molar teeth

Intervention groups

Intervention group: cyanoacrylate tissue adhesive will use in intervention group for wound closure. Control group: Silk suture will use in control group by simple interrupted suture techniqe.

Main outcome variables

Pain,wound dehiscence,vascularity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191030045286N1**
Registration date: **2020-05-12, 1399/02/23**
Registration timing: **retrospective**

Last update: **2020-05-12, 1399/02/23**
Update count: **0**

Registration date

2020-05-12, 1399/02/23

Registrant information

Name

mahsa farokhnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5234 3015

Email address

farokhnia.ma@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

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
Comparison of Silk Sutures and Tissue Adhesives for wound closure of Impacted Third Molar Teeth surgery: Clinical and Histological Evaluation

Public title
Investigation of effects of tissue adhesive on Impacted Third Molar Teeth surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All subjects of 18 years and above with mesio-angularly impacted mandibular third molar Subjects whitout known systemic disease such as bleeding dyscrasia and immunosuppression Subjects not allergic to the drugs or anaesthetic agents in the surgical protocol Subjects with good oral hygiene Subjects who are non-smokers

Exclusion criteria:
Subject with severe caries of the second molar teeth Subject between the age of 18 & 25 who have vertical class 1 and level A pell & gregory classification impaction in third molar teeth

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
After impacted mandibular third molar surjery,one side will be closed with tissue adhesive and the other side will be closed with silk suture

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is simply individual and is done by random number table,even numbers are for group A (suture) and odd numbers are for group B (tissue adhesive).We close our eyes and select the number by our finger,If the even number is selected, we close the wound of right side of the jaw with sutures and if odd number is selected,we close the wound of that side of the jaw with tissue adhesive.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahvaz Jondishapur university of medical science

Street address
Jondishapur university of medical science,Esfand St.,farvardin Ave.,Glestan

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ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2019-07-27, 1398/05/05

Ethics committee reference number
IR.AJUMS.REC.1398.340

Health conditions studied

1

Description of health condition studied
Impactd teeth

ICD-10 code
K01.1

ICD-10 code description
Impacted teeth

Primary outcomes

1

Description
pain

Timepoint
1,3,7 days after surgery

Method of measurement
by pain Visual Analogue Scale

2

Description
Wound dehiscence

Timepoint
1,3,7 days after surgery

Method of measurement
by visual inspection and by gentle probing with a williams probe

3

Description
vascularity

Timepoint

7days after surgery

Method of measurement

By microscope

Secondary outcomes

1

Description

Swelling

Timepoint

Befor surgery and 1,3,7 days after surgery

Method of measurement

Average of tragus to pogonion,tragus to commissure and external canthus to gonion

2

Description

Trismus

Timepoint

Before surgery and 1,3,7 days after surgery

Method of measurement

Maximum space between mesial and incisal edge of central teeth of maxilla and mandible

3

Description

Bleeding

Timepoint

1,3,7days after surgery

Method of measurement

Visual Analogue Scale

4

Description

Wound infection

Timepoint

1,3,7 days after surgery

Method of measurement

Based on purulent discharge from the surgical site

5

Description

Wound closure time

Timepoint

during surgery

Method of measurement

Recording by using a calibrated stop watch

6

Description

Inflammatory cell infiltration

Timepoint

7days after surgery

Method of measurement

By microscope

7

Description

Fibroblastic activity

Timepoint

7days after surgery

Method of measurement

By microscope

Intervention groups

1

Description

Intervention group: 2-ethyl-cyanoacrylate tissue adhesive(EPIGLU,Meyer-Haake Co.Germany) will be used in intervention group for surgery wound closure.Tissue adhesive will be used based on the instructions on the package.

Category

Treatment - Surgery

2

Description

Control group: Non-Absorbable 3/0 silk suture will be used in control group by simple interrupted suture techniqe for surgery wound closure.(SUPASIL Non-Absorbable 3/0 braided silk suture,SUPA MEDICAL DEVICES,Iran)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school,Ahvaz University of Medical Science

Full name of responsible person

Shahrokh Raisian

Street address

Oral and Maxillofacial surgery department of Ahvaz dental school,dental school,Dey St.,Farvardin Ave.,Golestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mahsa Farokhnia
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

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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

Not applicable