Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of amniotic membrane in reduction of postoperative complications after impacted mandibular third molar surgery

Protocol summary

Summary

Purpose. surgical removal of impacted mandibular third molar is one of the most common surgical procedures in the oral cavity which usually accompanies with predictable sequels such as bleeding, swelling, pain and trismus. The aim of this study is to use amniotic membrane as a biological dressing into the socket of extracted mandibular third molar and review its relationship with complications such as pain, swelling and trismus. Study design. Randomized, double-blind, placebo-uncontrolled, single-center, phase one trial. The methodology of the study. In this split mouth study, 26 patients referred to Hamadan dental school with the age range of 64-16 years old with impacted mandibular third molars who had bilaterally and similar impacts are to be reviewed. In this study, the side of the mandible where amniotic membrane is placed inside, it will be considered as the treatment side while the opposite side is control that is randomly selected for each patient. At least 4 weeks interval is considered between surgeries on either side to ensure recovery of the surgery. Surgery and amniotic membrane insertion is implemented by maxillofacial surgeon but the variables were examined by student who is blind to placement or non-placement of amniotic membrane and for this reason this study is blinded both on the patient and the inspector person. Pain level is recorded with VAS scale, swelling is evaluated by inflexible tape by UStün method and trismus is measured by assessing the interincisal distance by digital caliper on 2, 5 and 8 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071228892N1**
Registration date: **2016-10-02, 1395/07/11**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-10-02, 1395/07/11

Registrant information

Name

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Name of organization / entity

dental school,Hamadan universiity of medical sciences

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of amniotic membrane in reduction of postoperative complications after impacted mandibular third molar surgery

Public title

Effect of amniotic membrane in reduction of postoperative complications after impacted mandibular

third molar surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: taking no medications and drugs; healthy patients with ASA 1 category; lack of allergy to local anesthesia; having bilateral mandibular third molar with similar impaction Exclusion criteria: poor oral hygiene; hypersensitivity to amniotic membrane; smoking and alcohol abuse; pregnant and lactating mothers

Age
From **16 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan University of Medical Sciences

Street address
Shahid Fahmideh Street, Hamadan City, Hamadan, Iran

City
Hamadan

Postal code

Approval date
2016-07-02, 1395/04/12

Ethics committee reference number
IR.UMSHA.REC.1395.180

Health conditions studied

1

Description of health condition studied
Correlation between complications associated with impacted mandibular third molar surgery and amniotic membrane

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain

Timepoint
days 2 , 5 , 8

Method of measurement
VAS scale

2

Description
swelling

Timepoint
days 2 , 5 , 8

Method of measurement
Sum of 3 distances: 1- tragus to oral commisure; 2- lateral canthus to mandibular angle; 3- tragus to pogonion

3

Description
trismus

Timepoint
days 2 , 5 , 8

Method of measurement
Maximum opening measured between upper and lower incisors

Secondary outcomes

1

Description
patient satisfaction

Timepoint
days 2, 5, 8

Method of measurement
based on planned scale

Intervention groups

1

Description
In this study, side of mandible in which amniotic membrane is applied, is considered treatment group and would be selected randomly for each patient. Surgical removal of contralateral wisdom tooth would be performed at least 4 weeks after first surgery. Fresh amniotic membrane can be preserve into normal saline up to 24 hours. Amniotic membrane is settled into the socket in layered fashion.

Category

Treatment - Other

2

Description
Contralateral side is considered control.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental School, Hamadan University of Medical Sciences
Full name of responsible person
Street address
Shahid Fahmideh Street, Hamadan City, Hamadan, Iran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan University of Medical Sciences
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Shahid Fahmideh Street, Dental School, Hamadan, Iran
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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
Hamadan 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

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Person responsible for updating data

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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