

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of local tranexamic acid versus placebo on the incidence of dry socket after mandibular impacted wisdom teeth surgery: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of local tranexamic acid versus placebo on the incidence of dry socket after mandibular impacted wisdom teeth surgery

Design

This is a double-blind randomized clinical trial, phase II, in which 25 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with bilateral Mandibular impacted wisdom teeth who will refer to the School of Dentistry in Hamadan city during the study period will be enrolled in the trial and the left and right sides of the patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that neither patients nor the physician will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 30 years, Bilateral Mandibular impacted wisdom teeth, Exclusion criteria: Presence of infection or inflammation around the hidden teeth, Poor oral hygiene, Allergy to topical anesthesia, Analgesic and antibiotic use, Taking oral contraceptive pills, Smoking and drug use, Using antidepressants medications

Intervention groups

Intervention group: Surgery of mandibular impacted wisdom teeth on one side plus placement of gel foam including tranexamic acid Control group: Surgery of mandibular impacted wisdom teeth on one side plus placement of gel foam including normal saline

Main outcome variables

The severity of pain, elimination of blood clots, mouth odor, the severity of swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N313**

Registration date: **2019-10-22, 1398/07/30**

Registration timing: **retrospective**

Last update: **2019-10-22, 1398/07/30**

Update count: **0**

Registration date

2019-10-22, 1398/07/30

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of local tranexamic acid versus placebo on the incidence of dry socket after mandibular impacted wisdom teeth surgery: a double-blind randomized clinical trial

Public title

Effect of local tranexamic acid versus placebo on the incidence of dry socket after mandibular impacted wisdom teeth surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 30 years, Bilateral Mandibular impacted wisdom teeth,

Exclusion criteria:

Presence of infection or inflammation around the hidden teeth, Poor oral hygiene, Allergy to topical anesthesia, Analgesic and antibiotic use, Taking oral contraceptive pills, Smoking and drug use, Using antidepressants medications

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the right and left sides of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "right" on one sheet and "left" on another. Then, by referring to every patient, one of the sheets will be randomly taken. According to whether the sheet is taken right or left is assigned to the intervention group and the other side to the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as triple-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-12-01, 1397/09/10

Ethics committee reference number

IR.UMSHA.REC.1397.634

Health conditions studied

1

Description of health condition studied

Impacted wisdom teeth

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description

The severity of pain

Timepoint

On the third, seventh and fourteenth days after surgery

Method of measurement

Using Visual Analogue Scale (VAS)

2

Description

Elimination of blood clots

Timepoint

On the third, seventh and fourteenth days after surgery

Method of measurement

By clinical examination

3

Description

Mouth odor

Timepoint

On the third, seventh and fourteenth days after surgery

Method of measurement

By clinical examination

4

Description

The severity of swelling

Timepoint

On the third, seventh and fourteenth days after surgery

Method of measurement

By clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Surgery of mandibular impacted wisdom teeth on one side plus placement of gel foam including tranexamic acid

Category

Treatment - Drugs

2

Description

Control group: Surgery of mandibular impacted wisdom teeth on one side plus placement of gel foam including normal saline

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

School of Dentistry in Hamadan city

Full name of responsible person

Dr. Tanaz Raeipoor

Street address

School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Hamedan University of Medical Sciences

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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Tanaz Raeipoor

Position

Dentistry Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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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