

# 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)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

t\_ra30pour@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**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

**Street address**

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

**City**

Hamadan

**Province**

Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0572  
**Email**  
t\_ra30pour@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Amir Hussein Babaeisoroor  
**Position**  
Oral and maxillofacial surgeon  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0572  
**Email**  
dr.amirsoroor@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**

Dr. Jalal Poorolajal  
**Position**  
Professor of Epidemiology  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Epidemiology  
**Street address**  
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0090  
**Email**  
poorolajal@umsha.ac.ir

## 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