

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

**Comparison of the effect of tranexamic acid washing solution with gel foam impregnated with tranexamic acid (TXA) on the amount of bleeding time after wisdom tooth surgery in all healthy patients between 20 and 60 years old who require bilateral extraction of mandibular wisdom teeth**

### Protocol summary

#### Study aim

Determining the comparison of the effect of using a washing solution containing tranexamic acid with Gelfoam impregnated with tranexamic acid (TXA) on the amount of bleeding after wisdom tooth surgery.

#### Design

A clinical trial without a control group with parallel groups, randomized with randomization website, with a sample size of 42 healthy patients between 20 and 60 years old.

#### Settings and conduct

wisdom tooth surgery on one side of the mandible and silent tooth washing using tranexamic acid solution (10 cc 150 mg), then suturing and measuring the bleeding time (we put sterile gauze every one minute until its color turns pink and go down) Then wisdom tooth surgery on the other side and placing Gelfoam impregnated with tranexamic acid (10 cc 150 mg), then suturing and measuring the bleeding time (we put sterile gauze every one minute until the color turns pink and decreases) and Finally, these two methods are compared. On the 3rd, 7th, and 14th days after surgery, patients are examined for pain. All samplings are done in the clinic of Jundishapur Dental School in Ahvaz.

#### Participants/inclusion and exclusion criteria

Healthy patients between 20 and 60 years old who have bilateral mandibular wisdom teeth

#### Intervention groups

First intervention: wisdom tooth surgery on one side of the mandible and silent tooth washing using a washing solution containing tranexamic acid (10 cc 150 mg) and measuring the bleeding time. The second intervention: surgery on the opposite tooth of the same person and placing Gelfoam impregnated with tranexamic acid (10 cc 150 mg) and measuring the bleeding time.

#### Main outcome variables

Bleeding time after wisdom tooth surgery  
Pain after surgery

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20231127060206N1**

Registration date: **2023-12-05, 1402/09/14**

Registration timing: **prospective**

Last update: **2023-12-05, 1402/09/14**

Update count: **0**

#### Registration date

2023-12-05, 1402/09/14

#### Registrant information

##### Name

Arsalan Saki

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3336 6215

##### Email address

sakiarsalan@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-12-08, 1402/09/17

#### Expected recruitment end date

2023-12-28, 1402/10/07

#### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of tranexamic acid washing solution with gel foam impregnated with tranexamic acid (TXA) on the amount of bleeding time after wisdom tooth surgery in all healthy patients between 20 and 60 years old who require bilateral extraction of mandibular wisdom teeth

**Public title**  
Comparison of the effect of tranexamic acid washing solution with gel foam impregnated with tranexamic acid (TXA) on the amount of bleeding time after wisdom tooth surgery

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
all healthy patients between 20 and 60 years old With bilateral mandibular wisdom teeth  
**Exclusion criteria:**  
Patients with underlying problems and diseases Patients with coagulation problems Non-committed and uncooperative patients Physically and mentally disabled patients

**Age**  
From **20 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **42**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**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**

Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

### **Street address**

Faculty of dentistry , jundishapur university of medical science , esfand st , Golestan

### **City**

Ahvaz

### **Province**

Khouzestan

### **Postal code**

6135715775

### **Approval date**

2023-11-25, 1402/09/04

### **Ethics committee reference number**

IR.AJUMS.REC.1402.443

## Health conditions studied

### 1

#### **Description of health condition studied**

Measuring the bleeding time after wisdom tooth surgery after using tranexamic acid in solution form and gelfoam impregnated with tranexamic acid in two separate sockets of mandibular wisdom teeth and comparing these two methods at the end and also measuring pain on days 3, 7 and 14 From surgeryCommunity Verified icon

#### **ICD-10 code**

#### **ICD-10 code description**

## Primary outcomes

### 1

#### **Description**

bleeding time

#### **Timepoint**

Every minute after the intervention

#### **Method of measurement**

Using sterile gas and changing the color and amount of blood on it after every minute

## Secondary outcomes

### 1

#### **Description**

Measurement of pain after surgery

#### **Timepoint**

Day 3, 7 and 14 after surgery

#### **Method of measurement**

using visual analogue scale

## Intervention groups

### 1

#### **Description**

Intervention group: In all healthy patients between 20 and 60 years old. Washing one of the sockets of the

mandibular wisdom tooth after tooth extraction using a washing solution containing tranexamic acid (10 cc 150 mg). Placing gelfoam impregnated with tranexamic acid (150 mg) in another socket after tooth extraction.

**Category**

Prevention

**2**

**Description**

Intervention group: Intervention group: Gelfoam impregnated with tranexamic acid (10 cc 150 mg) is placed in the same patient as before and in another patient.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ahvaz Jundishapur University Dental Clinic

**Full name of responsible person**

Mahdis Masoudrad

**Street address**

faculty of dentistry clinic , Ahvaz jundishapour university of medical sciences , esfand st , golestan , Ahvaz , Khoozestan , Iran

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fdentistry@ajums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mahsid Masoudrad

**Street address**

faculty of dentistry clinic , Ahvaz jundishapour university of medical sciences , esfand st , golestan , Ahvaz , Khoozestan , Iran

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**Grant name**

Vice Chancellor for Research, Research and Technology, Jundishapur University of Medical Sciences, AhvazCommunity Verified icon

**Grant code / Reference number**

گرنٲ استفاده نشده است

**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**

Arsalan Saki

**Position**

student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

Mahdis Masoudrad

**Position**

Associate professor

**Latest degree**

Specialist

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**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

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**Position**

student

**Latest degree**

A Level or less

**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

All data is shareable after de-identifying individuals

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

All interested people in various related fields can apply to receive them

**Under which criteria data/document could be used**

The analyzes that are going to be done have been done in line with the research

**From where data/document is obtainable**

By e-mail sakiarsalan@gmail.com

**What processes are involved for a request to access data/document**

Someone who is an expert and interested, along with a document, send a request via electronic mail, explaining the reason for the need for the data and what is to be done on the data, and the reason for the interest.

**Comments**