Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Street address

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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

گرنت 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

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Position

Associate professor

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Person responsible for updating data

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Latest degree
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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