

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comprasion of the Effect of dilute hydrogen peroxide and tranexamic acid with local application of gas on control of bleeding after tooth extraction in patients using aspirin

Protocol summary

Study aim

Comparison of bleeding control status after tooth extraction after local use of gases impregnated with diluted hydrogen peroxide and gases impregnated with tranexamic acid

Design

A clinical trial with a control group, with parallel groups, double-blind, non-randomize ,phase 3 on 24 patients

Settings and conduct

The place of study is Alborz School of Dentistry. For patients, three maxillary teeth are extracted. And the patients' teeth are evaluated in the following three groups: After entering, the patients' teeth are randomly divided into the desired groups, including the local application of gas impregnated with diluted hydrogen peroxide and tranexamic acid, as well as the control group. Each group is examined by the surgeon and the patient himself for the type of medicine used in 0 and 15 minutes. They will not know

Participants/Inclusion and exclusion criteria

Inclusion criteria Teeth with deep decay and teeth that are extracted due to periodontal reasons are removed non-surgically Exit criteria Patients with systemic diseases Patients using aspirin more than 80 mg

Intervention groups

For patients, three maxillary teeth are extracted. And the patients' teeth are evaluated in the following three groups: After entering, the patients' teeth were randomly divided into the desired groups, including the local application of gas impregnated with diluted hydrogen peroxide and tranexamic acid, as well as the control group. In the first group, gas impregnated with hydrogen peroxide, in the second group, gas impregnated with tragrammic acid, and in the control group, gas without coagulant is placed, and each group keeps the gas in place for 10 and 15 minutes.

Main outcome variables

Investigating the effectiveness of gases impregnated with diluted hydrogen peroxide and tranexamic acid in bleeding control and its clinical application on aspirin consuming patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230828059283N1**

Registration date: **2023-08-29, 1402/06/07**

Registration timing: **prospective**

Last update: **2023-08-29, 1402/06/07**

Update count: **0**

Registration date

2023-08-29, 1402/06/07

Registrant information

Name

RAZIYEH Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 990 626 1634

Email address

sarataheri196@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comprasion of the Effect of dilute hydrogen peroxide and tranexamic acid with local application of gas on control of bleeding after tooth extraction in patients using aspirin

Public title
Investigating the effectiveness of gases impregnated with diluted hydrogen peroxide and tranexamic acid in bleeding control and its clinical application on aspirin consuming patients.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Teeth with deep decay and teeth that are extracted due to periodontal reasons and removed non-surgically. Patients without other systemic diseases and non-smokers.

Exclusion criteria:
Patients with systemic diseases and the use of anticoagulant drugs except aspirin and smokers, teeth with periodontal problems and the need for open surgery during treatment. Unknown internal coagulation disorders factors Qualitative and quantitative platelet problems Taking other anticoagulant drugs by the patient History of hemophilia Patients using aspirin more than 80 mg

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **3**
For the examined patients, three maxillary teeth are extracted

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The surgeon and the patient will not know the type of medicine used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Alborz University of Medical Sciences

Street address
Safarian Alley, 45 meters from Golshahr, Karaj

City
karaj

Province
Alborz

Postal code
319876465

Approval date
2023-08-12, 1402/05/21

Ethics committee reference number
IR.ABZUMS.REC.1402.143

Health conditions studied

1

Description of health condition studied

Comprasion of the effect of dilute hydrogen peroxide and tranexamic acid with local application of gas on control of bleeding after tooth extraction in patients using aspirin

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Active bleeding:Bleeding refers to bleeding that does not form a clot after a period of 2 to 9 minutes and is continuous

Timepoint
10 to 15 minute

Method of measurement
Clinical examinations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the desired group 1, two gauzes soaked in 10 ml of diluted hydrogen peroxide solution (1%) prepared by the pharmacy technician (by adding 3.3 ml of water with 6.6 ml of 1.5% hydrogen peroxide) is

kept in place for 10 and 15 minutes immediately after tooth extraction

Category

Treatment - Drugs

2

Description

Intervention group: In the target group 2, two gauzes impregnated with tranexamic acid solution after tooth extraction in the form of 10 ml tranexamic acid solution and two ampoules of tranexamic acid 50 mg/5 ml with a concentration of 4.8% immediately after tooth extraction for It is kept in place for 10 to 15 minutes

Category

Treatment - Drugs

3

Description

Control group: control group: . In the control group, after tooth extraction, without using any local coagulant, the patient is asked to keep the two gauzes in place for 10 and 15 minutes using two sterile gauzes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Alborz University of Medical Sciences

Full name of responsible person

RAZIYEH Taheri

Street address

Shahid Katoizade St, 45 meters, Golshahr, Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj 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?

No

Title of funding source

The cost is covered by the student

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

RAZIYEH Taheri

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Latest degree

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Other areas of specialty/work

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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