Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparative Evaluation of the effect of tranexamic acid impregnated gauze with gelatamp in controlling bleeding after the extraction of four maxillary primary incisors in children candidates for dental treatment under general anesthesia

Protocol summary

Study aim
Comparative Evaluation of the effect of tranexamic acid impregnated gauze with gelatamp in bleeding control

Design
Randomized cross over trial on 30 patient, double-blind, This study will be conducted in a double-blind manner so that the examining clinician and data analyst will not know the type of intervention.

Settings and conduct
Children candidates for dental treatment under general anesthesia who refer to the hospital dental department of Isfahan Faculty of Dentistry during the study, if they are eligible, will be included in the study and will be randomly divided with the help of a random number table.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: The need to Extract Primary incisors, Age 2 to 4 years, The Studied Teeth should have less than One-third root resorption and unmaintainable crowns, The Child under Study only needs to have four Primary incisors Extracted and no other teeth should be Extracted from the Patient If the Tooth is not infected and the root has not Decayed to a large extent, it is included in the study Exclusion Criteria: History of any uncontrolled systemic disease, Patients whose parents do not consent to participate in the study for any reason

Intervention groups
Intervention group 1: Gelatamp, two pieces of gelatamp (Spongostan, Ferrosan, Denmark) will be placed half inside the socket. Intervention group 2: Tranexamic acid-impregnated gauze, 2x2 gauze impregnated with 4cc of Tranexamic acid ampoule (Tranexip, Caspian Tamin, Iran) with a dose of 500 mg/5 ml will be applied to two adjacent teeth.

Main outcome variables
Intensity of Bleeding, Bleeding Time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210419051016N3**
Registration date: **2023-06-17, 1402/03/27**
Registration timing: **retrospective**

Last update: **2023-06-17, 1402/03/27**
Update count: **0**

Registration date
2023-06-17, 1402/03/27

Registrant information

Name
Maryam Hajiahmadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-16, 1402/01/27

Expected recruitment end date
2023-06-17, 1402/03/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparative Evaluation of the effect of tranexamic acid impregnated gauze with gelatamp in controlling bleeding after the extraction of four maxillary primary incisors in children candidates for dental treatment under general anesthesia

Public title
Comparative Evaluation of the effect of tranexamic acid impregnated gauze with gelatamp in controlling bleeding

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The need to Extract Primary incisors Age 2 to 4 years Children are not affected to Congenital Hemorrhagic Diseases Children should not receive Anticoagulants The Child does not have a Mental or Physical Disability The Studied Teeth should have less than One-third root Resorption and unmaintainable Crowns Do not take Ibuprofen and Aspirin Painkillers before and after work The Child does not have Contraindications for General Anesthesia The Studied Child only needs to have four Primary incisors Extracted and another Tooth Extracted from the Patient If the Tooth is not Infected and the root has not Decayed to a large extent, it is included in the Study If They do not have Complications during General Anesthesia. (Hypoxia, Blood Pressure drop, Larynx Spasm, etc.)

Exclusion criteria:
History of any uncontrolled systemic disease Patients whose parents do not consent to participate in the study for any reason

Age
From **2 years** old to **4 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Children who are candidates for extraction of primary teeth who refer to the hospital dental department of Isfahan Faculty of Dentistry during the study, if they are eligible, will be included in the study and will be randomly assigned by simple randomization method and individually with the help of a table of random numbers; In this method, the 'AB' order is considered for each odd number, and the 'BA' order is considered for each even number. Then a column is randomly selected from the table and if the first selected number is odd, the 'AB' order is applied which means the first patient is allocated in the A group and receives GELATAMP treatment, and as a result, the next patient is allocated to the B group and receives TRANEXAMIC ACID IMPREGNATED GAUZE treatment. Similarly, If the selected number is even, the 'BA' order is applied and the first patient is allocated in the B group and receives TRANEXAMIC ACID IMPREGNATED GAUZE treatment, and as a result, the next patient is allocated to the A group and receives GELATAMP treatment. This is repeated 15 times until you get 15 samples in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Outcome assessor was not aware of the type of material used for each tooth while evaluating the treated teeth clinically and radiographically. This study will be conducted in a double-blind manner so that the examining clinician and data analyst will not know the type of intervention.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Ground Floor, Faculty of Medicine, Building No. 3, Isfahan University of Medical Sciences,Hezar Jerib St., Isfahan , Phone number: 03137923080

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81746-73461

Approval date
2023-03-18, 1401/12/27

Ethics committee reference number
IR.MUI.RESEARCH.REC.1401.433

Health conditions studied

1

Description of health condition studied
Tranexamic Acid, Controlling Bleeding, Gelatamp

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of Bleeding
Timepoint
The determined time intervals are 10, 5, and 15 minutes after starting to use Gelatamp and gauze impregnated with Tranexamic acid
Method of measurement
Fanning scale

2

Description
Bleeding Time
Timepoint
The determined time intervals are 10, 5, and 15 minutes after starting to use Gelatamp and gauze impregnated with Tranexamic acid
Method of measurement
Fanning scale

Secondary outcomes

1

Description
Oral Health
Timepoint
At the beginning of the study (before the start of the intervention) and Two weeks after the end of the intervention
Method of measurement
Examination of the child's mouth

Intervention groups

1

Description
The first intervention group: Gelatamp, after extraction for two teeth, two pieces of Gelatamp (Spongostan, Ferrosan, Denmark) will be placed half inside the socket and after a period of 4 weeks in the second phase of the study, the groups will be changed.
Category
Treatment - Other

2

Description
The second intervention group: Tranexamic acid impregnated gauze, a gauze with dimensions of 2 x 2, impregnated with 4cc of ampoule of tranexamic acid (Tranexip, Caspian Tamin, Iran) with a dose of 500 mg/5 ml will be applied to two similar teeth and after a period of 4 weeks in the second phase of the study, the groups will be changed.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Hospital Dentistry, Faculty of Dentistry, Isfahan
Full name of responsible person
Dr.Maryam Hajiahmadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Maryam Hajiahmadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

The patient's personal details are not required

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

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

In case of research on a similar subject, they can use the data of this research

From where data/document is obtainable

Correspondance with Dr. HajiAhmadi via e-mail dr.maryamhajiahmadi@gmail.com

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

Correspondance with Dr. HajiAhmadi via e-mail and documents will be sent if she agrees

Comments