

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation the Effects of Echium Amoenum Tea on Pain Control after Clinical Crown lengthening Surgery

#### Protocol summary

##### Study aim

Evaluation of the effects of Echium amoenum tea on pain control after clinical crown lengthening surgery

##### Design

A clinical trial will with a placebo group, with parallel groups, two-blind, randomized. A randomized sampling from among individuals referring to the periodontology department of Tabriz Dental School. Types of treatment with code A (Echium Amoenum Tea) and B (placebo) are marked and placed in a bag. Then it was accidentally select from the bag and after the code is seen, the treatment will be given to the patient. Sample size will consist of 50 people.

##### Settings and conduct

The intervention group 24 hours before surgery every 12 hours, once and one hour before the start of surgery, will use a dose of Echium Amoenum Tea. The placebo group will use water as a placebo. The amount of pain will measure 30 minutes, 1, 3, 24, 48 and 72 hours after surgery.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having conscious awareness, Patients who are candidates for surgery can increase the length of the crown of the tooth, Ages from 20 to 65 years old, Patients with moderate to severe periodontitis at the same depth of the envelope Exit criteria: Patients with systemic or mental illness, Alcoholism or any psychoactive substance, Sensitization known to be NSAID, caffeine or acetaminophen, Having any bleeding disorder, Patients at risk for any post-surgical infection, Patients with liver problems, Patients with a heart and blood pressure problems, Patients who need to increase the dose of sedative or injectable forms of sedative

##### Intervention groups

The intervention group 24 hours before surgery every 12 hours, once and one hour before the start of surgery, will use a dose of Echium Amoenum Tea. The placebo group will use water as a placebo.

##### Main outcome variables

The amount of pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180630040290N3**

Registration date: **2019-07-30, 1398/05/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-07-30, 1398/05/08**

Update count: **0**

##### Registration date

2019-07-30, 1398/05/08

##### Registrant information

##### Name

Amir Reza Babaloo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3428 3025

##### Email address

babalooa@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-11, 1398/04/20

##### Expected recruitment end date

2019-08-01, 1398/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation the Effects of Echium Amoenum Tea on Pain Control after Clinical Crown lengthening Surgery

### Public title

Evaluation the Effects of Echium Amoenum Tea on Pain Control after Clinical Crown lengthening Surgery

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having conscious awareness Patients who are candidates for surgery can increase the length of the crown of the tooth (in the posterior maxilla). ages from 20 to 65 years old Patients who are physically and mentally healthy Patients with moderate to severe periodontitis at the same depth of envelope

#### Exclusion criteria:

Patients with systemic or mental illness Alcoholism or any psychoactive substance Sensitization known to be NSAID, caffeine or acetaminophen Having any bleeding disorder Patients at risk for any post-surgical infection Patients with liver problems Patients with a heart and blood pressure problems Persons with mental and physical disabilities (persons who do not have the competence to satisfy their personal satisfaction and complete the questionnaires) Patients who use of Echium Amoenum Tea are risky for them Patients who need to increase the dose of sedative or injectable forms of sedative Patients with no needs for bone surgery

### Age

From **20 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Outcome assessor

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Sampling Method is randomly among Individuals referring to the Periodontics Department of Tabriz Dental faculty. The randomization Method is simple and the unit is individual, our tool for randomization is the randomized Number Chart. Furthermore, the Allocation of Echium Amoenum tea or placebo to patients is done randomly. To do this, the types of treatments are identified with code A (Echium Amoenum tea) and B (placebo) and then they will be placed in a Box and stirred. Then they are randomly chosen from the Box and after observing the code, the treatment is given to the Patient. None of the Patients will be informed about another Patient's treatment.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Present Study is conducted in double-blinded fashion. Both Echium Amoenum tea and placebo will be in similar envelopes ( the same shape, size and color ).Sampling Method is randomly among Individuals referring to the Periodontics Department of Tabriz Dental faculty. The randomization Method is simple and the unit is individual, our tool for randomization is the randomized Number Chart. Furthermore, the Allocation of Echium Amoenum tea or placebo to patients is done randomly. To do this, the types of treatments are identified with code A (Echium Amoenum tea) and B (placebo) and then they will be placed in a Box and stirred. Then they are randomly chosen from the Box and after observing the code, the treatment is given to the Patient. None of the Patients will be informed about another Patient's treatment.The placebo group is treated in the same way as the intervention group, but instead of the Echium Amoenum tea, they will use ordinary water as a placebo. Contributors are unaware of the many types of treatment in the study and they are not aware of the other participants. The evaluator is also unaware of the type of treatment.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Central office of Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165687386

#### Approval date

2019-07-01, 1398/04/10

#### Ethics committee reference number

IR.TBZMED.REC.1398.373

## Health conditions studied

### 1

#### Description of health condition studied

Decrease the crown length of the tooth

#### ICD-10 code

K08.1

### ICD-10 code description

Loss of teeth due to accident, extraction or local periodontal disease

## Primary outcomes

### 1

#### Description

Extent of pain in the operated part

#### Timepoint

After 30 minutes, 1 and 3 hours after the operation , 1 and 2 and 3 days after the operation

#### Method of measurement

En 30 minutes, 1 and 3 hours after the operation by VAS(Visual Analogue Scale) , after 1 and 2 and 3 days by VRS(Verbal Rating Scale)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group 24 hours before surgery every 12 hours once , and one hour before the start of surgery, will use a dose of Echium Amoenum Tea.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The placebo group 24 hours before surgery every 12 hours once , and one hour before the start of surgery, will use water as placebo.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz University of Medical Sciences Dentistry  
Faculty Periodontics Department

##### Full name of responsible person

Amirreza Babaloo

##### Street address

Dentistry Faculty of Tabriz, Golgasht Ave, Azadi Blvd

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

#### Phone

+98 41 3335 5921

#### Email

amirrezababaloo@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Abolghasem Jouyban

##### Street address

Central office No. 2, Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd

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+98 41 3335 7310

##### Email

ajouyban@hotmail.com

##### Web page address

<https://researchvice.tbzmed.ac.ir>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Amir reza Babaloo

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Amir reza Babaloo

**Position**

Assistant Professor

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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