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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+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

Street address

Dentistry faculty, Tabriz University of Medical Sciences, Golgasht

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 5921

Email
amirezababaloo@yahoo.com

Person responsible for scientific 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

Street address
Dentistry faculty, Tabriz University of Medical Sciences, Golgasht Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 5921

Email
amirezababaloo@yahoo.com

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

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Dentistry faculty, Tabriz University of Medical Sciences, Golgasht Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 5921

Email
amirezababaloo@yahoo.com

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