

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Clinical trial of Evaluation of The Effect of Echium Amoenum Tea before Dental Implant surgery on Pre-surgical Anxiety Control and Post-surgical Pain Control

Protocol summary

Study aim

This study aimed to evaluate the effect of Echium Amoenum tea before dental implant surgery on pre-surgical anxiety control and post-surgical pain control.

Design

Fifty-four patients who needed dental implantation were chosen via simple randomization and categorized in two groups of equal size.

Settings and conduct

Both Echium Amoenum tea and placebo will be in similar packets (shape, size, color were similar), which is made by the Faculty of Pharmacy of Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

This study included the patients in the 25-50 age bracket who needed dental implantation; Patients with systemic or mental diseases, The patients for whom the intake of Echium Amoenum tea was harmful, and the patients with psychological and stress conditions, were excluded from this study.

Intervention groups

In the intervention group, Echium Amoenum tea (made at Faculty of Pharmacy of Tabriz University of Medical Sciences) was given to the patients 1 hour before implantation, and the morning following the implantation, the patients were asked to drink it again. Placebo (drinking water whose chemical neutrality was approved by Faculty of Pharmacy of Tabriz University of Medical Sciences) was given to the control group 1 hour before the start of implantation, and the morning following the implantation, they were asked to drink the placebo again. In both groups, patients filled in the manifest anxiety questionnaire just before the start of implantation. After the implantation, both groups will take the painkiller (600 mg of Ibuprofen, every 6 hours, for three days) according to the surgeon's order.

Main outcome variables

Extent of pain in the operated part after 30 minutes, 1 and 3 hours, 1 and 2 and 3 days after the operation.
Preoperative anxiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180630040290N1**

Registration date: **2018-07-15, 1397/04/24**

Registration timing: **prospective**

Last update: **2018-07-15, 1397/04/24**

Update count: **0**

Registration date

2018-07-15, 1397/04/24

Registrant information

Name

Amir Reza Babaloo

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Evaluation of The Effect of Echium Amoenum Tea before Dental Implant surgery on Pre-surgical Anxiety Control and Post-surgical Pain Control

Public title

Evaluation of The Effect of Echium Amoenum Tea before Dental Implant surgery on Pre-surgical Anxiety Control and Post-surgical Pain Control

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients in the 25-50 age bracket. The patients who needed dental implantation.

Exclusion criteria:

Patients with systemic or mental diseases. Patients with hemorrhagic, lever, cardiac and hypertension diseases. Pregnant and breastfeeding women. The patients for whom the intake of Echium Amoenum tea is harmful. The patients with psychological and stress conditions.

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Both Echium Amoenum tea and placebo will be in similar packets (shape, size, color were similar), which is made by the Faculty of Pharmacy of Tabriz University of Medical Sciences.

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, Goltasht Ave, Azadi Blvd

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East Azarbaijan

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5165687386

Approval date

2018-06-25, 1397/04/04

Ethics committee reference number

IR.TBZMED.REC.1397.263

Health conditions studied**1****Description of health condition studied**

Effect of Echium Amoenum Tea on Pre-surgical Anxiety Control and Post-surgical Pain Control

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Preoperative anxiety

Timepoint

Just before the start of surgery

Method of measurement

Spielberger's manifest anxiety questionnaire

Secondary 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

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)

Intervention groups**1****Description**

Intervention group: Echium Amoenum Tea (made at Faculty of Pharmacy of Tabriz University of Medical Sciences) was given to the patients 1 hour before implantation, and the morning following the

implantation, the patients were asked to drink it again. Patients filled in the Spielberg's manifest anxiety questionnaire just before the start of implantation.

Category

Treatment - Other

2

Description

Control group: Placebo (drinking water whose chemical neutrality was approved by Faculty of Pharmacy of Tabriz University of Medical Sciences) was given to the control group 1 hour before the start of implantation, and the morning following after the implantation, they were asked to drink the placebo again. Patients filled in the Spielberg's manifest anxiety questionnaire just before the start of implantation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic of Faculty of Dentistry of Tabriz

Full name of responsible person

Amirreza Babaloo

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

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

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Person responsible for scientific inquiries

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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

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