

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Evaluation The Efficacy of premedication of Passifloralncarnata Linnaeus Compared to placebo on patients' anxiety

#### Protocol summary

##### Study aim

The Efficacy of premedication of Passifloralncarnata Linnaeus in Reducing Dental Anxiety in Patients referred to endodontic department of dental faculty of Isfahan University of medical sciences in 2019-2020

##### Design

A single blind; randomized clinical trial with control group and parallel group design; with sample size of 78 patients

##### Settings and conduct

Place and time of research : the Isfahan Dental School, Autumn & Winter of 2019-2020 . In this study, patients were blinded. There is also a randomization in this study. For randomization numbers 1 through 3 are written on 78 sheets (1: Passiflora Incarnata 2: Placebo 3: No Medication) and patients are asked take one sheet by chance among the sheets and patients are unaware of their medication.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People whose score on the DAS-R Corah's Anxiety Rating System is above 9; adult. Non-inclusion criteria: drug use; gastrointestinal diseases; psychotropic drugs use; pregnancy; liver and blood problems; having hepatitis and HIV.

##### Intervention groups

Intervention group 1: Passifloralncarnata medication- Patients are given 25 drops of Passifloralncarnata.  
Intervention groups 2: placebo- 25 drops of placebo that is quite similar to the original drug, given to the patient.  
Control group: without medication- No medication is given to the control group.

##### Main outcome variables

Anxiety score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200127046277N1**

Registration date: **2020-03-26, 1399/01/07**

Registration timing: **retrospective**

Last update: **2020-03-26, 1399/01/07**

Update count: **0**

##### Registration date

2020-03-26, 1399/01/07

##### Registrant information

###### Name

ali ghazalgoo

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 5547

###### Email address

alighazalgoo@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

2019-09-23, 1398/07/01

##### Actual recruitment end date

2019-11-16, 1398/08/25

##### Trial completion date

2019-11-16, 1398/08/25

##### Scientific title

Evaluation The Efficacy of premedication of Passifloralncarnata Linnaeus Compared to placebo on patients' anxiety

##### Public title

The Efficacy of premedication of Passiflora Incarnata Linnaeus in reducing patients' anxiety

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients whose anxiety score is more than 9 based on the Corah questionnaire need root canal therapy

#### Exclusion criteria:

Psychotropic drugs usage Liver and blood problems  
Pregnancy Gastrointestinal diseases

### Age

From **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant

### Sample size

Target sample size: **78**

Actual sample size reached: **78**

### Randomization (investigator's opinion)

Randomized

### Randomization description

For randomization, 26 sheets of number 1 and 26 sheets of number 2 and 26 sheets of number 3 are written (1: Passiflora Incarnata 2: placebo 3: no medication) and patients are asked take out one sheet to write between sheets by chance.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

In this study, placebo is quite similar to the main drug and therefore patients will be kept unaware of their medication.

### Placebo

Used

### Assignment

Parallel

### 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

Dental College; Hezarjerib street

##### City

Isfahan

##### Province

Isfahan

### Postal code

8174673461

### Approval date

2019-12-25, 1398/10/04

### Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.555

## Health conditions studied

### 1

#### Description of health condition studied

anxiety

#### ICD-10 code

F06.4

#### ICD-10 code description

Anxiety disorder due to known physiological condition

## Primary outcomes

### 1

#### Description

Anxiety score

#### Timepoint

The night before treatment and 90 minutes before treatment

#### Method of measurement

questionnaire Corah's Dental Anxiety Scale (DAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Use of Passiflora-This group will receive the oral premedication of the Passiflora extract. These people will consume 25 drops of the Passiflora extract at the night before the visit and at least 90 minutes before arrival. The therapeutic effects of the Passiflora extract are related to Flavonoids, Alkaloids and sugars. Each 100 ml drop contains about 15 to 15 grams of total flavonoids in terms of hyperoside. The Passiflora extract is produced by Irandarok Pharmaceutical Company.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: These patients will consume 25 drops of placebo which is completely similar to the extract of the Passiflora, at the night before the visit and at least 90 minutes before the arrival.

#### Category

Placebo

### 3

#### Description

Control group: Do not take any medication

#### Category

Diagnosis

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Dental College of Isfahan University of Medical Sciences

###### Full name of responsible person

Dr. Ali Ghazaloo

###### Street address

Dental College; Hezarjerib street

###### City

Isfahan

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7461766998

###### Phone

+98 31 3792 5547

###### Email

alighazaloo@yahoo.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Esfahan University of Medical Sciences

###### Full name of responsible person

Dr. Nakisa Torabinia

###### Street address

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research@mui.ac.ir

###### 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

Ali Ghazaloo

###### Position

Professor

###### Latest degree

Specialist

###### Other areas of specialty/work

Dentistry

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### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Esfahan University of Medical Sciences

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Ali Ghazaloo

###### Position

Associate professor

###### Latest degree

Specialist

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Kaffashi

**Position**

Student

**Latest degree**

A Level or less

**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