

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Nakisa Torabinia

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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

Ali Ghazaloo

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Kaffashi

Position

Student

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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