Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the effect of chamomile(matricaria chamomilla) extract on severity of anxiety before root canal therapy in anxious patient

Protocol summary

Study aim
Determining the prodrug effect of chamomile extract (Matarcaria camomila) on the severity of anxiety before endodontic treatment in anxious patients referred to the endodontic department of Isfahan Dental School

Design
A double-blind randomized controlled clinical trial Sample size 64 people, simple randomization with random number table

Settings and conduct
After explaining the research process to the patient and completing the consent, the patient completes the Modified Dental Anxiety Questionnaire (MDAS). If the score is 11 or higher, the patient is anxious. Then, if the patient is in the control group, consumes 130ml of ordinary water and if the patient is in the intervention group, consumes 30oral drops of chamomile extract in 100 ml of ordinary water. After 60minutes, the anxiety questionnaire is completed again by patients in both groups

Participants/Inclusion and exclusion criteria
Samples of patients referred to the endodontic department of Isfahan Dental School are selected and randomly divided into two categories of intervention and control. Inclusion criteria: The patient is anxious, be mentally healthy and have the ability to fill out the questionnaire, have not used sedatives, the patient has no history of allergies to chamomile, the patient does not have asthma The patient should not take warfarin

Intervention groups
In the control group, the patient consumes 130ml of normal water in a disposable glass with a door whose contents are not visible and in the intervention group, according to the instructions of the manufacturer, the patient takes 30oral drops of chamomile extract produced by Sina Faravar Pharmaceutical Company with the name of Kamazol and the standard mark and drug registration number is 8675081546681476 in 100ml of normal water in a disposable glass with a door whose contents are not visible.

Main outcome variables
Anxiety score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210516051320N1**
Registration date: **2021-08-11, 1400/05/20**
Registration timing: **retrospective**

Last update: **2021-08-11, 1400/05/20**
Update count: **0**

Registration date
2021-08-11, 1400/05/20

Registrant information

Name
mohammad torabizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3628 8528

Email address
torabizadeh@dnt.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-07-23, 1400/05/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of chamomile(matricaria chamomilla) extract on severity of anxiety before root canal therapy in anxious patient

Public title

Evaluation of the effect of chamomile(matricaria chamomilla) extract on severity of anxiety before root canal therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

A patient volunteering for endodontic treatment who scores more than 11 and less than 19 on the Anxiety Scale Patient consent The patient has a healthy mental state and the ability to fill out a questionnaire

Exclusion criteria:

The patient has used sedatives The patient has a history of allergy to chamomile The patient has asthma The patient takes warfarin

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample size consists of 64 people who are randomly divided into two groups of 32 intervention and 32 control using the randomization block method. Using the site www.sealedenvelope.com and considering the 8 blocks, patients are divided.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants and the physician treating the patient are kept blind because disposable cups with a door that is not visible inside are used and are all coded for consumption in the control and intervention groups. Depending on which group the patient number belongs to, In the control group, the patient consumes 130 ml of normal water in a disposable glass with a door whose contents are not visible and in the intervention group, according to the instructions of the manufacturer, the patient takes 30 oral drops of chamomile extract produced by Sina Faravar Pharmaceutical Company with the name of Kamazol and the standard mark and drug registration number is 8675081546681476 in 100 ml of normal water in a disposable glass with a door whose contents are not visible. In order to eliminate the psychological effect of chamomile smell, the lids of all the glasses in both groups have been pre-soaked with 2 drops of chamomile extract.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Vice-Chancellor in Research Affairs -Medical University of Isfahan

Street address

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Building No. 4, Vice Chancellor for Research and Technology

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.836

Health conditions studied

1

Description of health condition studied

Anxiety before root canal treatment

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Anxiety score in MDAS questionnaire

Timepoint

Anxiety scores are measured in two stages before the intervention and one hour after

Method of measurement

Modified Dental Anxiety Questionnaire (MDAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, according to the instruction of the manufacturer. The patient consumes 30 oral drops of chamomile extract produced by Sina Faravar Pharmaceutical Company with the name of Kamazol and the standard mark and registration number of the drug is 86750815466681476 in 100 ml of ordinary water in a disposable glass with its contents invisible. In order to eliminate the psychological effect of chamomile smell, the lids of all the glasses in both groups are pre-soaked in cotton with 2 drops of chamomile extract.

Category
Prevention

2

Description
Control group: In the control group, the patient consumes 130 ml of ordinary water in a disposable glass with the contents not visible. In order to eliminate the psychological effect of chamomile smell, the lids of all the glasses in both groups have been pre-soaked with 2 drops of chamomile extract.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental school of Isfahan University of Medical Science

Full name of responsible person
Alireza Mousavifard

Street address
Hezar Jerib street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3071

Email
international@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Nakisa Torabinia

Street address
Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Building No. 4, Vice Chancellor for Research and Technology

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 7898

Email
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
Mohammad Torabizadeh

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
No. 127, Firooz dead end, Jamalzadeh, Mohtasham Kashani Ave.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3628 8528

Fax

Email
torabizadeh@dnt.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Torabizadeh
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No. 127, Firooz dead end, Jamalzadeh, Mohtasham Kashani Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3628 8528
Fax
Email
torabizadeh@dnt.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Torabizadeh
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No. 127, Firooz dead end, Jamalzadeh, Mohtasham Kashani Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3628 8528
Fax
Email
torabizadeh@dnt.mui.ac.ir

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