

# 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

Isfahan

##### 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

Isfahan

##### 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

Isfahan

#### 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

Isfahan

##### 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**

Isfahan

**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**

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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