

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Determination of the effect of Rosa damascene extract on anxiety of Emergency Medical Technicians

#### Protocol summary

##### Study aim

Investigating the Effect of Rose damascene extract on Anxiety

##### Design

This study is a Randomized clinical trial. The researcher, after approving and obtaining permission from the vice chancellor, the manager of the emergency center of 115 and the emergency bases authorities, began to investigate in and out of the city. He introduced the study to staff and explaining the study aim; then, obtaining written informed consent from the personnel by the project executor; the samples selected randomly based on the inclusion criteria. The allocation of treatment among them was done randomly by block randomization (Quad-blocks); so, 30 people were in the intervention group with rose extract and 30 people in the control group (placebo).

##### Settings and conduct

After selecting samples, the intervention group drink the Rose Syrup, twice daily for 6 weeks with 15 cc of Rose Syrup in half a glass of water. In the control group, the placebo will be used. In this study, Rose Syrup is composed of rose extract and sweet solution made from sugar; the placebo is also a sweet solution that does not have an extract of rose, which will be used in the control group. Due to the absence of a placebo similar to the extract of rose, there is no possibility of blinding in the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.All emergency medical technicians working in pre-hospital departments. Exclusion criteria: 1.Technicians who were not participate at all. 2. Those who have problems with indigestion or sensitivity to rose extract. 3. Those who use sedatives and similar medications for sedation

##### Intervention groups

The intervention and control groups selected from the emergency services technicians of 115; according to the inclusion criteria.

#### Main outcome variables

anxiety

#### General information

##### Reason for update

##### Acronym

عصاره گل سخ

##### IRCT registration information

IRCT registration number: **IRCT20150210021036N2**

Registration date: **2019-08-16, 1398/05/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-16, 1398/05/25**

Update count: **0**

##### Registration date

2019-08-16, 1398/05/25

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 37833821

##### Email address

rfarhadlu@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-23, 1398/05/01

##### Expected recruitment end date

2019-09-21, 1398/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Determination of the effect of Rosa damascene extract on anxiety of Emergency Medical Technicians

## Public title

Determination of the effect of Rosa damascene extract on anxiety of Emergency Medical Technicians

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All medical emergency technicians operating in pre-hospital emergency departments

### Exclusion criteria:

Technicians who are not willing to participate in the research. Technicians who have a problem with indigestion or anxiousness to the rose extract.

Technicians who use sedation suppressants and similar devices

## Age

From **20 years** old to **60 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

60 people are randomly selected from among qualified entry and exit criteria. Then, randomly, the names of the staff and the number of couples in the intervention group and the individual numbers in the control group are selected for each group.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

##### Street address

No83-Safashahr Street4-Qom

#### City

Qom

#### Province

Ghoush

#### Postal code

37169-93456

#### Approval date

2019-06-11, 1398/03/21

#### Ethics committee reference number

lr.muq.rec.1398.035

## 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

#### Timepoint

Before the intervention and 6 weeks after the intervention begins

#### Method of measurement

Standard questionnaire eshpeal berger

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For individuals in the intervention group; 30 people with Rosa damascene syrup twice a day for 6 weeks each time with 10 cc of Rosa damascene syrup prepared per day in traditional medicine in half a glass of water.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: For individuals in the control group; 30 people without Rosa damascene syrup twice a day for 6 weeks each time with 10 cc prepared per day in traditional medicine in half a glass of water. Control group: In the control group instead of Rosa damascene, a placebo that is a syrup without Rosa damascene is used.

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Emergency115

**Full name of responsible person**

Farhadloo Roohollah

**Street address**

Num18-Honarestan38

**City**

Qom

**Province**

Ghoum

**Postal code**

37158-37593

**Phone**

+98 25 3783 3821

**Email**

Rfarhadlu@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ghoum University of Medical Sciences

**Full name of responsible person**

Hossein Saghafi

**Street address**

Number83-Safashahr4-Qom

**City**

Qom

**Province**

Ghoum

**Postal code**

37196-93456

**Phone**

+98 25 3285 2720

**Email**

Dr.Hosseinsaghafi@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ghoum 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**

Ghoum University of Medical Sciences

**Full name of responsible person**

Roohollah Farhadloo

**Position**

Employee

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

**Street address**

Number18-Honarestan38-Qom

**City**

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**Province**

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**Postal code**

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Rfarhadlu@gmail.com

## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Roohollah Farhadloo

**Position**

Employee

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Roohollah Farhadloo

**Position**

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**Latest degree**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The project data will include demographic variables such as age, age, marital status, and anxiety disorder.

**When the data will become available and for how long**

Two months after the results

**To whom data/document is available**

Researchers at universities and colleges and universities

**Under which criteria data/document could be used**

Doing any kind of analysis on the data is also available.

To access data, send a written request and the subject of the data application field.

**From where data/document is obtainable**

1-rfarhadlu@gmail.com 2-mobile 09127575116(roohollah farhadloo)

**What processes are involved for a request to access data/document**

Two weeks after the submission of the written request, the data can be provided through the published postal address.

**Comments**