Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 سرخ

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
Ghoum

Postal code
37169-93456

Approval date
2019-06-11, 1398/03/21

Ethics committee reference number
Ir.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
Qom
Province
Ghoum
Postal code
37158-37593
Phone
+98 25 3783 3821
Email
Rfarhadlu@gmail.com

Person responsible for scientific 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
No18-Honarestan38-Qom
City
Qom
Province
Ghoum
Postal code
37158-37593
Phone
+98 25 3783 3821
Email
Rfarhadlu@gmail.com

Person responsible for updating data

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
Qom
Province
Ghoum
Postal code
37158-37593
Phone
+98 25 3783 3821
Email
Rfarhadlu@gmail.com

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