

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of rose water on the anxiety level and Hemodynamic index of elderly admitted to cardiac care unit

Protocol summary

Registration timing: **prospective**

Study aim

Determine the effectiveness of rose water on the anxiety level and Hemodynamic index of elderly admitted to cardiac care unit

Last update: **2018-09-01, 1397/06/10**

Update count: **0**

Registration date

2018-09-01, 1397/06/10

Design

Clinical trial with control group, randomized, parallel group design with 52 patients

Registrant information

Name

Maryam Jadid Milani

Name of organization / entity

Nursing Faculty of Shahed University

Country

Iran (Islamic Republic of)

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Settings and conduct

Patients will be selected from the cardiac intensive care unit of Shaheed Mostafa Khomeini Hospital, Tehran, Iran. In control group, 40 cc of water will be placed in container at the patient's bedside table. The intervention group, 40 cc of rose water will be placed in container at the patient's bedside table. These procures will be done in two nights from 22 to 6 o'clock in the morning.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having cardiac disease; More than 60 years old; Desired cognitive status: Having cognition health (score higher than 7 based on Cognitive Short Test); No history of allergy to medicinal herbs; lack of asthma and any respiratory distress recorded in the file. Exclusion criteria: Participating simultaneously in similar study

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

In control group, 40 cc of water will be placed in container at the patient's bedside table. The intervention group, 40 cc of rose water will be placed in container at the patient's bedside table. These procures will be done in two nights from 22 to 6 o'clock in the morning.

Main outcome variables

Anxiety level; Hemodynamic index

Scientific title

The effect of rose water on the anxiety level and Hemodynamic index of elderly admitted to cardiac care unit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170313033047N2**

Registration date: **2018-09-01, 1397/06/10**

Public title

The effect of rose water on the anxiety level and

Hemodynamic index

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age older than 60 years Having cognition health (score higher than 7 based on Cognitive Short Test) No history of allergy to medicinal herbs lack of asthma and any respiratory distress recorded in the file
Exclusion criteria:
 Participating simultaneously in similar study

Age
From 60 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 52

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random method by flipping a coin will be used to determine the test and control groups. Then, convenience sampling method will be used for sampling within groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
There are two groups in research: intervention and control. Both of them will receive routine care. In intervention group, inhalation of rose water will be used by patients .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.Shahed.REC.1396.123

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety Score on Hamilton's Anxiety Rating Scale

Timepoint

Measurement of anxiety at the beginning of the study (before the intervention), on the morning of the second day and on the morning of the third day

Method of measurement

Hamilton's Anxiety Rating Scale

2

Description

Blood pressure

Timepoint

Measurement of blood pressure at the beginning of the study (before the intervention), on the morning of the second day and on the morning of the third day

Method of measurement

Mercury pressure gauge device

3

Description

Heart rate

Timepoint

Measurement of heart rate at the beginning of the study (before the intervention), on the morning of the second day and on the morning of the third day

Method of measurement

Watch

4

Description

Respiratory rate

Timepoint

Measurement of respiratory rate at the beginning of the study (before the intervention), on the morning of the second day and on the morning of the third day

Method of measurement

Watch

Secondary outcomes

empty

Intervention groups

1

Description

Control group: For two nights, 40 ml of ordinary water will be placed in a disposable bowl on the bedside table and will remain beside the patient from 22:00 to 6 am. Intervention group: For two nights, 40 ml of rose water will be placed in a disposable bowl on the bedside table and will remain beside patient from 22:00 to 6 am. As the scent of the rose water will spread in the area and could have an effect on the outcome of the study in the control group, two groups cannot be selected at the same time. Therefore, flipping a coin will be used to determine which group will be started first. Based on the coin, whichever group wins will be the first to start. After the research is conducted on the initial group which won the coin, sampling will be done for the next group. But, if the first group was the intervention group, sampling of control group will be started after three days. This three day period would ensure complete removal of any traces of the rose water scent in the study environment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Mostafa Khomeini Hospital

Full name of responsible person

Dr Faramarz Falahi

Street address

Italy Ave, Felestine Ave, Shaheed Mostafa Khomeini Hospital

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1416643491

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+98 21 8890 6130

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far910@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran

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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

Shahed University

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

Shahed University

Full name of responsible person

Maryam Jadid-Milani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

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Position

Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Maryam Jadid-Milani

Position

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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

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The research report will be presented as a dissertation and article

When the data will become available and for how long

Get started since November 1397

To whom data/document is available

researchers

Under which criteria data/document could be used

By citing to the dissertation or the research article in this study, they can use it.

From where data/document is obtainable

Maryam Jadid_Milani milani2000ir@yahoo.com

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

Sending e-mail to Maryam jadid-Milani

Comments