

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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)

##### Phone

+98 21 6641 8589

##### Email address

milani@shahed.ac.ir

#### 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.

#### Scientific title

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

#### Main outcome variables

Anxiety level; Hemodynamic index

#### Public title

The effect of rose water on the anxiety level and

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170313033047N2**

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

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 Khomini Hospital

##### Full name of responsible person

Dr Faramarz Falahi

##### Street address

Italy Ave, Felestine Ave, Shaheed Mostafa Khomini Hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1416643491

##### Phone

+98 21 8890 6130

##### Email

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

#### City

Tehran

#### Province

Tehran

#### Postal code

3319118651

#### Phone

+98 21 5121 5106

#### Email

kiasalari@shahed.ac.ir

#### 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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

3319118651

##### Phone

+98 21 51210

##### Email

milani2000ir@yahoo.com

## Person responsible for scientific

## **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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

3319118651

**Phone**

+98 21 51210

**Email**

milani2000ir@yahoo.com

## **Person responsible for updating data**

### **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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

3319118651

**Phone**

+98 21 51210

**Email**

milani2000ir@yahoo.com

## **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**