Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the lemon essence with placebo on anxiety, blood pressure, and electrocardiogram changes in patients with acute myocardial infarction

Protocol summary

Study aim

The comparison of lemon essence with placebo on anxiety, blood pressure and electrocardiogram changes in patients with acute myocardial infarction

Design

A clinical trial with control group, parallel group randomised trial with blinded outcomes

Settings and conduct

The settings of the study would be CCU wards in Faghihi, and Namazi hospital and AlZahra Heart Center affiliated to Shiraz University of Medical Sciences. In this study, a person who collects the outcomes of the study, as well as a statistician and health care provider, will be blind until the end of the study and completion of the data analysis and reporting.

Participants/Inclusion and exclusion criteria

The inclusion criteria were having acute myocardial infarction, being 18 years old or above, speak Persian language and oriented to time, person and place. The patients who have had an asthma, a respiratory allergy or be sensitive to extracts of the plant; who have had olfactory problems, and nasal injury; who have being known case of psychological diseases (major depression, anxiety, psychosis, etc.); who have had previous cardiovascular diseases, old myocardial infarction, and performed coronary artery bypass surgery, and Percutaneous transluminal coronary angioplasty; who have had previously arrhythmia (atrial fibrillation, ventricular atrial block, left and right heart block and ...); who have had chronic bronchitis, atelectasis, and other chronic respiratory diseases; who participated in previous studies received complementary and alternative interventions from a week before the intervention would be excluded.

Intervention groups

Take five drops of lemon essence on a cotton pad and put it in an open box at a distance of 20 centimeters of the patients. This essence is used at 8:30, 10:30, 12:30, 14:30, 16:30, 18:30 and 20:30 hours.

Main outcome variables

Anxiety, blood pressure, and electrocardiogram changes

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20130616013690N5**
Registration date: **2018-09-22, 1397/06/31**
Registration timing: **prospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **3**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Masoume Rambod

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4258

Email address

rambodm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-13, 1397/09/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the lemon essence with placebo on anxiety, blood pressure, and electrocardiogram changes in patients with acute myocardial infarction

Public title

Effect of the lemon essence on patients with acute myocardial infarction

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of acute myocardial infarction according to patient records Patients with 18 years old or above be able to speak in Persian language being oriented to time, person and place

Exclusion criteria:

Patient has an asthma, a respiratory allergy or be sensitive to extracts of the plant the patient had olfactory problems, and nasal injury being known case of psychological diseases (major depression, anxiety, psychosis, etc.) having previous cardiovascular diseases, old myocardial infarction, and performed coronary artery bypass surgery, Percutaneous transluminal coronary angioplasty Presence of previously recognized arrhythmia (atrial fibrillation, ventricular atrial block, left and right heart block and ...) having chronic bronchitis, atelectasis, and other chronic respiratory diseases Participated in previous studies received complementary and alternative interventions from a week before the intervention

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering the use of lemon essence and the probability of distribution of odor in the CCU ward and its effect on the control group, the CCU wards would be divided into an intervention and control groups, randomly. In order to this, ten CCU wards (three wards in Faghihi hospital, three wards in Nemazi hospital, and four in AlZahra Heart Center) would be divided into two the intervention and control groups, and based on block randomization with two wards per block, they would assigned into the intervention or control groups

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the person who evaluates the outcome, the healthcare staff , and the statistician would be remained blind into the groups. For this purpose, all of the above individuals would be blind into the groups until the analysis of the data is complete and reported.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shiraz University of Medical Sciences

Street address

Vice chancellor for research affairs, seven floor, Shiraz University of Medical Science, beside Helal Ahmar, Zand Ave, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-07-29, 1397/05/07

Ethics committee reference number

IR.SUMS.REC.1397.412

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction

ICD-10 code

121

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Anxiety
Timepoint
30 minutes before the intervention and four days after the intervention at 8:00 A.M.
Method of measurement
Spielberger State-Trait Anxiety Inventory (STAI)

Secondary outcomes

1

Description
Blood pressure
Timepoint
30 minutes before the intervention and every day from second to fourth days at 8 A.M.
Method of measurement
Digital heart monitoring device

2

Description
Electrocardiogram changes
Timepoint
30 minutes before the intervention and every day from second to fourth days at 8 A.M.
Method of measurement
Digital heart monitoring device

Intervention groups

1

Description
Intervention group: Take five drops of lemon essence on a cotton pad and put it in an open box at a distance of 20 centimeters of the patients. This essence is used at 8:30, 10:30, 12:30, 14:30, 16:30, 18:30 and 20:30 hours. Lemon essence would receive from Ahura-Daro Shiraz company with its certificate.
Category
Prevention

2

Description
Control group: Five drops of liquid paraffin are put on cotton at a distance of 20 cm from the patient's head, and this paraffin is used at 8:30, 10:30, 12:30, 14:30, 16:30, 18:30 and 20: 30.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faghihi and Namazi hospital and Alzahra Heart Center
Full name of responsible person
Masoume Rambod
Street address
Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz
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7193613119
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Basir Hashemi
Street address
Vice chancellor for research affairs of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
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71348-14336
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+98 71 3647 4258
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Masoume Rambod
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Title and more details about the data/document
Main outcomes
When the data will become available and for how long
2018-19
To whom data/document is available
University institutes
Under which criteria data/document could be used
The data can only be accessed by the journal that want to publish the article and no further use is permitted.
From where data/document is obtainable
In order to access to the data, contact to Email: rambodma@yahoo.com
What processes are involved for a request to access data/document
In order to access to the data, contact to Email: rambodma@yahoo.com
Comments