

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Effect of citrous Aurantium aroma on anxiety, stress and hemodynamic indices of acute coronary syndrome patients

Protocol summary

Study aim

1. Effect of Citrous Aurantium aroma on anxiety and hemodynamic parameters of patients with acute coronary syndrome.

Design

In this study, the target population is the patients with acute coronary syndrome admitted to Alameh Behnol Hospital in Gonabad. Sampling method is also simple random, The sample size is 80 patients. This is a phase 2-3 clinical trial.

Settings and conduct

The location of this intervention is Allameh Bohlol Hospital in Gonabad. In this one-blind study, the patient knew about the types of substances used during the intervention but did not know the type of substance to be used in each session. In the intervention group, three drops of 10% orange spring extract were poured onto the absorbent cloth attached to the patient's collar and we wanted to inhale it for 20 minutes.

Participants/Inclusion and exclusion criteria

Confirmation of acute coronary syndrome by cardiologist, having reading and writing skills, mental health, company satisfaction with research, lack of history of allergy to plants, lack of olfactory problems

Intervention groups

The intervention and control group includes both patients who have been diagnosed with acute coronary syndrome by the cardiologist.

Main outcome variables

Stress; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171219037966N1**

Registration date: **2018-03-19, 1396/12/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-11, 1397/05/20**

Update count: **1**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Amirreza Nasirzadeh

Name of organization / entity

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-06, 1396/06/15

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

2017-09-12, 1396/06/21

Actual recruitment end date

2018-04-19, 1397/01/30

Trial completion date

empty

Scientific title

Effect of citrous Aurantium aroma on anxiety, stress and hemodynamic indices of acute coronary syndrome patients

Public title

Effect of citrous Aurantium aroma on anxiety, stress and hemodynamic indices of acute coronary syndrome patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of acute coronary syndrome by a cardiologist having reading and writing skills mental health satisfaction with the presence in the research having no history of allergy to plants lack of olfactory problems

Exclusion criteria:

the patient's death the occurrence of any medical problem requiring immediate medical intervention during the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Use the method of permuted block randomization Using binary blocks A and B Which is by referring to the random numbers table If the number was odd, then the AB pattern would be used if the pattern of BA was even.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the intervention and recording of the results, the researcher assisted the blind researcher. The data analyzer was also blinded by ignorance of groupings

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Iran, Gonabad, Asian Roads, Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2017-04-10, 1396/01/21

Ethics committee reference number

IR.GMU.REC.1396.17

Health conditions studied

1

Description of health condition studied

Acute coronary syndrome

ICD-10 code

I20-I25

ICD-10 code description

Ischaemic heart diseases

Primary outcomes

1

Description

state Anxiety

Timepoint

Before the intervention and the first day after the intervention and the second day after the intervention

Method of measurement

Spielberger Anxiety questionnaire

2

Description

Adjectival anxiety

Timepoint

Before the intervention and the first day after the intervention and the second day after the intervention

Method of measurement

Spielberger Anxiety questionnaire

3

Description

stress

Timepoint

Before the intervention and the first day after the intervention and the second day after the intervention

Method of measurement

PSS-4 cohen stress questionnaire

4

Description

blood pressure

Timepoint

Before, five, thirty-sixty minutes after the intervention

Method of measurement

Digital SADAT Blood Pressure Measurement Device

5

Description

pulse oximetry

Timepoint

Before, five, thirty-sixty minutes after the intervention

Method of measurement

Monitoring device

6

Description

temperature

Timepoint

Before, five, thirty-sixty minutes after the intervention

Method of measurement

Welch Allyn tympanic thermometer

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, the patients inhaled three drops of 10% essential oil on an absorbent cloth attached to the patient's collar for 20 minutes.

Category

Treatment - Drugs

2

Description

Control group: In the placebo group, patients inhaled three drops of distilled water on the absorbent tissue cloth attached to their collars.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational Center, Allameh Bhlol Gonabadi Medical Research Center

Full name of responsible person

Hamid Dehqan Haqiqi

Street address

Vahdat Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Sajjadi

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Amirreza Nasirzadeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Mehdi Basiri Moghaddam

Position

MSc of Nursing

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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