

# 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

Iran (Islamic Republic of)

###### Phone

+98 51 5722 3028

###### Email address

nasirzadeh@gmu.ac.ir

##### 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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Gonabad

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**Postal code**

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**Email**

Nasirzadeharnz@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Ali Sajjadi

**Street address**

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

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moallef@gmail.com

**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**

Nursery

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## Person responsible for updating data

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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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**Email**

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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