

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of rhythmic breathing on chest pain and cardiorespiratory parameters Acute Coronary Syndrome patients admitted at CCU

Protocol summary

Summary

This study is a clinical trial to determine the effect of rhythmic breathing on the chest pain and cardiorespiratory parameters in patients with acute coronary syndrome (ACS) admitted to cardiac care unit (CCU). The study sample consist of 112 patients diagnosed with acute coronary syndrome and the inclusion criteria are: (ACS definitive diagnosis by the cardiologist; the lack of critical state of health; etc). The subjects will be selected of the CCU CHAMRAN hospital in Tehran in 2014 and will be randomized into intervention and control groups. The demographic and disease questionnaire will be completed for each patient. The intervention group will do the rhythmic breathing for twenty minutes every five minutes once and it will take a minute. In this way that the patient with closed eyes will be supine state and with counting numbers 1, 2 and 3 will enter air through the nose into the lungs, then by counting 1, 2 and 3 will keep the air in their lungs and finally, by counting 1, 2 and 3 will out the air through the mouth. Within twelve hours of admission to hospital, if chest pain occurs, in both groups the pain intensity will be measured by the McGill questionnaire and cardiorespiratory parameters will be monitored too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411097225N2**
Registration date: **2014-12-15, 1393/09/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-15, 1393/09/24

Registrant information

Name

Narges Saber

Name of organization / entity

Gonabad Uneversity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 53 3822 7703

Email address

n.saber@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rhythmic breathing on chest pain and cardiorespiratory parameters Acute Coronary Syndrome patients admitted at CCU

Public title

The effect of rhythmic breathing on Acute Coronary Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Volunteer for research; ACS definitive diagnosis by the cardiologist; Lack of critical state of health (no cardiac dysrhythmia, hemodynamic and

peripheral capillary oxygen saturation less than 80%)
licensed clinician; Non-smoking; Lack of alcoholism and
drug; Lack of respiratory diseases, gastrointestinal,
diabetes and mental recognized and diagnosed by a
physician; Age between 15-85 years Exclusion criteria:
Lack of satisfaction for cooperation; Create a life-
threatening situation; The creation of any intervening
circumstances that made it impossible to continue

Age

From **8 years** old to **92 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Asian road,
Gonabad, Khorasan Razavi, Iran

City

Gonabad

Postal code

Approval date

2014-05-22, 1393/03/01

Ethics committee reference number

gmu.rec.1393.5

Health conditions studied

1

Description of health condition studied

Acute Coronary Syndrome

ICD-10 code

I20.0

ICD-10 code description

Unstable angina

2

Description of health condition studied

Acute Coronary Syndrome

ICD-10 code

I21.0

ICD-10 code description

Acute transmural myocardial infarction of anterior wall

3

Description of health condition studied

Acute Coronary Syndrome

ICD-10 code

I21.1

ICD-10 code description

Acute transmural myocardial infarction of inferior wall

4

Description of health condition studied

Acute Coronary Syndrome

ICD-10 code

I21.2

ICD-10 code description

Acute transmural myocardial infarction of other sites

5

Description of health condition studied

Acute Coronary Syndrome

ICD-10 code

I21.3

ICD-10 code description

Acute transmural myocardial infarction of unspecified
site

6

Description of health condition studied

Acute Coronary Syndrome

ICD-10 code

I21.4

ICD-10 code description

Acute subendocardial myocardial infarction

7

Description of health condition studied

Acute Coronary Syndrome

ICD-10 code

I21.9

ICD-10 code description

Acute myocardial infarction, unspecified

Primary outcomes

1

Description

Chest pain

Timepoint

Before and during 12 hours after intervention.

Method of measurement

McGill pain scale

2

Description

Systolic and diastolic blood pressure

Timepoint

Before and during 12 hours after intervention.

Method of measurement

Monitoring

3

Description

Respiratory rate

Timepoint

Before and during 12 hours after intervention.

Method of measurement

Monitoring

4

Description

Respiratory rythme

Timepoint

Before and during 12 hours after intervention.

Method of measurement

Monitoring

5

Description

Pulse rate

Timepoint

Before and during 12 hours after intervention.

Method of measurement

Monitoring

6

Description

Pulse rythme

Timepoint

Before and during 12 hours after intervention.

Method of measurement

Electrocardiogram

7

Description

peripheral capillary oxygen saturation

Timepoint

Before and during 12 hours after intervention.

Method of measurement

Pulse oxymeter

8

Description

The need for drug

Timepoint

Before and during 12 hours after intervention.

Method of measurement

Patient pan card

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will do the rhythmic breathing for twenty minutes every five minutes once and it will take a minute and during their breathing will focus only on entering and leaving air. In this way that the patient will be supine state with eyes closed and with counting numbers 1, 2 and 3 will enter air through the nose into the lungs, then by counting 1, 2 and 3 will keep the air in their lungs and finally, by counting 1, 2 and 3 will out the air through the mouth.

Category

Other

2

Description

In control group, the intervention will not take place except routine treatments.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Chamran Hospital of Tehran

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Narges Saber

Street address

Gonabad University of Medical Sciences, Asian road,
Gonabad, Khorasan Razavi, Iran

City

Gonabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Investigator

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Narges Saber

Position

Msc student in intensive care nursing

Other areas of specialty/work**Street address**

Gonabad University of Medical Sciences, Asian road,
Gonabad, Khorasan Razavi, Iran

City

Gonabad

Postal code**Phone**

+98 51 5722 3514

Fax**Email**

n.saber@gmu.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Narges Saber

Position

Bachelor of Science Degree in Nursing, Msc student in
intensive care nursing

Other areas of specialty/work**Street address**

Gonabad University of Medical Sciences, Asian road,
Gonabad, Khorasan Razavi, Iran

City

Gonabad

Postal code**Phone**

+98 51 5722 3514

Fax**Email**

n.saber@gmu.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Narges Saber

Position

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Postal code**Phone**

+98 51 5722 3514

Fax**Email**

n.saber@gmu.ac.ir

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty