

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effect of Valsalva maneuver during arterial sheath removal on pain intensity in patients undergoing coronary artery angioplasty

#### Protocol summary

##### Study aim

The purpose of this study is to investigate the effect of Valsalva's maneuver during arterial catheter withdrawal on the severity of pain in patients undergoing coronary angioplasty.

##### Design

Clinical trials with randomized control group

##### Settings and conduct

This is a clinical trial in which eligible patients undergoing angioplasty in Tehran's Mohab Hospital. In the test group, the arterial sheet is removed during the Valsalva maneuver and in the control group removed it without any intervention.

##### Participants/Inclusion and exclusion criteria

Age between 40 to 70 years, angioplasty through the femoral artery ,conscious patients, having the ability to communicate, the lack of a history of drug use, the respiratory problems, cerebral problems, glaucoma, lack of high intra cranial brain pressure , recent eye surgery

##### Intervention groups

In the test group the patients performed a Valsalva maneuver it means blowing in a plastic tube connected to a mercury column and raise the mercury column 25-20 mmHg for at least 10 seconds and at the same time,the sheath will be removed

##### Main outcome variables

The pain of the patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110430006342N8**

Registration date: **2019-01-26, 1397/11/06**

Registration timing: **prospective**

Last update: **2019-01-26, 1397/11/06**

Update count: **0**

##### Registration date

2019-01-26, 1397/11/06

##### Registrant information

###### Name

Ali Asghar Ghods

###### Name of organization / entity

Semnan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 1335 4192

###### Email address

aaghods@sem-ums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-04, 1397/11/15

##### Expected recruitment end date

2019-06-05, 1398/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Valsalva maneuver during arterial sheath removal on pain intensity in patients undergoing coronary artery angioplasty

##### Public title

Effect of Valsalva maneuver on pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age between 40 to 70 years Angioplasty through the femoral artery Conscious patients, having the ability to communicate lack of a history of drug use lack of history of respiratory problems, cerebral problems, glaucoma, lack of high intra cranial brain pressure , recent eye surgery

**Exclusion criteria:**

Patients who don't have the ability to perform the Valsalva maneuver, through the holding mercury column above than 20 mm hg for 10 seconds, patients with radial artery access and , , or Patients who tried to enter the needle several times Patients with an arterial sheath larger than 6 french Patients who have dangerous arrhythmia, or hemodynamic problems

**Age**

From **40 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment of samples in groups is done using random numbers of 24 possible modes. This random selection is placed in each of the four blocks, which are based on age (55-40, 70-56) and gender. Each number will determine four consecutive samples in each block of age and gender.

**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**

Ethics committee of Semnan University of Medical Sciences

**Street address**

Basij Street, Headquarters of Semnan University of Medical Sciences, Deputy Director of Research and Technology

**City**

Semnan

**Province**

Semnan

**Postal code**

۹۹۹۵۱- ۳۵۱۹۸

**Approval date**

2019-01-15, 1397/10/25

**Ethics committee reference number**

IR.SEMUMS.REC.1397.232

**Health conditions studied**

**1**

**Description of health condition studied**

Acute ischaemic heart disease

**ICD-10 code**

I24.9

**ICD-10 code description**

Acute ischemic heart disease, unspecified

**Primary outcomes**

**1**

**Description**

Intensity of pain

**Timepoint**

Before and after intervention

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: In the test group, at first the patient is requested blowing a plastic tube attached to the sphygmomanometer and hold the mercury column at 25-20 mm Hg for 10 seconds, and at the same time, the arterial sheet is removed by a experienced nurse.

**Category**

Treatment - Other

**2**

**Description**

Control group: Without any intervention, according to the routine, arterial catheter will be removed by an experienced nurse

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Moheb Mehr Hospital

**Full name of responsible person**

Akram Roshani

**Street address**

Valiasr Street - after Vanak Square - Khalilzadeh Alley

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۶۹۷۱۳۱۹۹

**Phone**

+98 21 85555

**Email**

info@mohebmehrhospital.com

**Web page address**<http://mohebmehrhospital.com/index.jsp?siteid=1&fk eyid=&siteid=1&fk eyid=&siteid=1&pageid=341>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Parviz Kokhaee

**Street address**

Basij Street, Headquarters of Semnan University of Medical Sciences, Deputy Director of Research and Technology

**City**

Semnan

**Province**

Semnan

**Postal code**

۹۹۹۵۱- ۳۵۱۹۸.

**Phone**

+98 23 3344 1021

**Email**

info@semums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Ali Asghar Ghods

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing, Semnan University of Medical Sciences, Km 6 Damghan Road

**City**

Semnan

**Province**

Semnan

**Postal code**

1111111111

**Phone**

+98 23 3365 4170

**Email**

aaghods@yahoo.com

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

Semnan University of Medical Sciences

**Full name of responsible person**

Ali Asghar Ghods

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Km6 Damghan Road, Semnan University of Medical Sciences, Semnan, Faculty of Nursing

**City**

Semnan

**Province**

Semnan

**Postal code**

1111111111

**Phone**

+98 23 3365 4170

**Email**

aaghods@yahoo.com

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

Semnan University of Medical Sciences

**Full name of responsible person**

Ali Asghar Ghods

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing, Semnan University of Medical Sciences, Km 6 Damghan Road

**City**

Semnan

**Province**

Semnan

**Postal code**

35147-99442

**Phone**

+98 23 3365 4170

**Email**

aaghods@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**

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