Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the Efficacy of Entonox in Reducing Pain, Anxiety, and Radial Artery Spasm During Trans radial Coronary Angiography: A Randomized Controlled, single-blind study

Protocol summary

Study aim
Evaluation of the Efficacy of Entonox in Reducing Pain, Anxiety, and Radial Artery Spasm During Trans radial Coronary Angiography

Design
A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 118 patients, (two groups of 59 patients). For randomization, in order to prevent disruption of the routine process of the angiography unit and reduce personnel confusion, drug allocation is done on a time-based basis.

Settings and conduct
Place of performance: Angiography Department, Hajar Hospital, Shahrekord Initially: Providing necessary explanations, measuring and recording the patient's baseline condition before entering the catheter room Patients are subject to standard monitoring throughout the procedure. Before starting the procedure, the patient is fitted with a mask (Entonox gas / oxygen gas) and the procedure begins. At the end of the procedure, Entonox is discontinued and the patient returns to full consciousness within a few minutes. The patient's hand pain level and the patient's anxiety and satisfaction with the entire angiography experience are immediately measured. Blinding method: Single blind (participants will not be aware of the type of intervention received.)

Participants/Inclusion and exclusion criteria
Inclusion criteria: Stable and non-emergency patient Written informed consent Exclusion criteria: Contraindications to Entonox History of reaction to N2O Decreased level of consciousness

Intervention groups
In the control group, patients will only be given oxygen continuously at a constant flow rate of 3 to 5 liters per minute through a simple mask. In the intervention group, the mask will contain Entonox, which is delivered to the patient through a standard delivery system equipped with a Valve Demand.

Main outcome variables
Reduced risk of radial spasm or vasovagal symptoms; Hemodynamic stability; Speed of return to function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201028049181N5**
Registration date: **2026-08-24, 1405/06/02**
Registration timing: **prospective**

Last update: **2026-08-24, 1405/06/02**
Update count: **0**

Registration date
2026-08-24, 1405/06/02

Registrant information

Name
Pedram Babaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3441 1076

Email address
pedram.babaee70@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Efficacy of Entonox in Reducing Pain, Anxiety, and Radial Artery Spasm During Trans radial Coronary Angiography: A Randomized Controlled, single-blind study

Public title

Evaluation of the Efficacy of Entonox in Reducing Pain, Anxiety, and Radial Artery Spasm During Trans radial Coronary Angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 80 years Stable, non-emergency patient ASA Class I to III Possibility of using the Entonox mouthpiece or mask Patients who are candidates for elective angiography Written informed consent

Exclusion criteria:

Contraindications for Entonox (pneumothorax, intestinal obstruction, air embolism, ocular gas injection, increased ICP) Severe COPD Severe CHF History of reaction to NO Inability to cooperate or consume properly Decreased level of consciousness High pulmonary pressure Drug sensitivity

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **118**

Randomization (investigator's opinion)

Randomized

Randomization description

To avoid disruption to the routine of the angiography unit and to reduce staff confusion, drug allocation is time-based; on pre-determined days, all eligible patients receive a specific drug (for example, patients on Sunday receive a simple oxygen mask and patients on Tuesday receive an Entonox mask). This allocation is fixed for the entire study period and the proportion of patients in the two groups is considered equal in terms of the number of sessions.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, in order to reduce bias, a single-blind blinding method will be used. In this way, participants will not be aware of the type of intervention they will receive (Entonox gas/oxygen gas), while the researchers will be aware of the allocation of individuals to different groups. The allocation of samples to groups will be done randomly and the interventions will be presented in such a way that they will not be distinguishable to the participants in terms of appearance and method of consumption. This method is used to reduce psychological effects and participant response bias and increase the validity of the study results.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Hajar Hospital, University Headquarters, Parastar St., Kashani Blvd.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Approval date

2026-08-08, 1405/05/17

Ethics committee reference number

IR.SKUMS.MED.REC.1405.123

Health conditions studied

1

Description of health condition studied

Trans-radial angiograohy

ICD-10 code

I73

ICD-10 code description

Other peripheral vascular diseases

Primary outcomes

1

Description

Patient pain score

Timepoint

Immediately after the procedure is completed and the patient is fully conscious.

Method of measurement

Visual Analogue Scale 0 -10

2

Description
Patient anxiety score throughout the procedure
Timepoint
Immediately after the procedure is completed and the patient is fully conscious.
Method of measurement
Short Spielberger Inventory (6-STAI)

3

Description
Severity of spasm
Timepoint
During angiography
Method of measurement
Based on the standard definition 0 to 4(rathore score)

Secondary outcomes

1

Description
Vasovagal
Timepoint
During angiograohy
Method of measurement
Diagnosis based on physician's opinion

Intervention groups

1

Description
Control group: The mask contains only simple oxygen, and the patient would have no way of knowing what type of gas was being inhaled, given the lack of a specific odor.
Category
Placebo

2

Description
Intervention group: The mask contains a pre-mixed, fixed 50:50 Entonox mixture, which is delivered to the patient via a standard delivery system equipped with a Demand Valve.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar hospital of Shahrekord Univesity of medical sciences
Full name of responsible person
Pedram Babaee
Street address
Parastar street, Kashani street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۵۷۱۳۴۷۱
Phone
+98 38 3222 5505
Email
pedram.babaee70@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. Ali Hassanpour
Street address
Building No. 2; University Headquarters; Kashani Blvd.
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3334 2414
Email
research@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Pedram Babaee
Position
Associate professor

Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Unit 7, 1st Block (Right Side), Asatid Residential Complex, Shahrekord University of Medical Sciences Central Headquarters, Kashani St., Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8365788157
Phone
+98 38 3222 5505
Fax
Email
Pedram.babaee70@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Pedram Babaee
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Postal code
8365788157
Phone
+98 38 3222 5505
Fax
Email
Pedram.babaee70@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Pedram Babaee
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Unit 7, 1st Block (Right Side), Asatid Residential Complex, Shahrekord University of Medical Sciences Central Headquarters, Kashani St., Shahrekord
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Postal code
8365788157
Phone
+98 38 3222 5505
Fax
Email
Pedram.babaee70@gmail.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