

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of Effects of two Pharmacological and Non-pharmacological methods on the Vasospasm, Pain, and Anxiety of Patients undergoing Radial Angiography

#### Protocol summary

##### Summary

The aim of the study is the comparative assessing of two pharmaceutical and nonpharmaceutical methods on vasospasm, pain, and anxiety of patients undergoing of radial angiography. The study is a clinical trial with the control group and random design. The main inclusion criteria are having the 15-65 years old and not existing critical situation and not using sedatives. The main exclusion criteria are appearing of serious complications during angiography and existing contradictions in getting pethidine. The sample size is 30 in each group and in all three groups is 90 (2 intervention groups and 1 control groups) that they will be allocated randomly by blocking method among three groups. The first random allocation will be done by lottery. Two interventions will be included the followings: in group 1 Benson relaxation technique will be educated and done during 15-20 minutes and in the group 2, the 25 mg pethidine was infused intravenously half an hour before angiography. At control group won't be done any intervention. Assessment and intervention will be started the half an hour before angiography. The pain and anxiety outcomes will be assessed in half an hour before and in the end of angiography. Also during angiography, vasospasm, and pain will be assessed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017071324312N2**

Registration date: **2017-10-15, 1396/07/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-15, 1396/07/23

##### Registrant information

###### Name

Fataneh Ghadirian Baharanchi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellor for research, Baqiyatallah University of Medical Sciences

##### Expected recruitment start date

2016-10-25, 1395/08/04

##### Expected recruitment end date

2017-08-21, 1396/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Effects of two Pharmacological and Non-pharmacological methods on the Vasospasm, Pain, and Anxiety of Patients undergoing Radial Angiography

##### Public title

The effects of Pharmacological and Non-pharmacological methods on the Radial Artery Spasm in Radial Angiography

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Allen positive test; Age between 15-65 years; No previous history of radial angiography; Having no cognitive impairment before and after the intervention; Having no emergency condition; Having no extra anxiety in patient; Having satisfaction; lack of hearing impairment; Having at least reading and writing skills; No having used tranquilizers during the last 8 hours" Exclusion criteria: A history of sedative medicine; History of neurological and respiratory problems; History of paralysis and paresthesia in patients; History of substance abuse or similar drugs such as oral methadone; The occurrence of any hematoma and radial arterial perforation during radial angiography; History of liver & kidney disorders

## Age

From **14 years** old to **64 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **90**

## 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

Ethics Committee of Baqiyatallah University of Medical Sciences

##### Street address

Nosrati Alley, South Sheykhbahee St., Mollasadra St.,

##### City

Tehran

##### Postal code

14155-6427

#### Approval date

2016-10-16, 1395/07/25

#### Ethics committee reference number

IR.BMSU.REC.1395.94

## Health conditions studied

### 1

#### Description of health condition studied

Vasospasm

#### ICD-10 code

I73.9

#### ICD-10 code description

Peripheral vascular disease, unspecified

## Primary outcomes

### 1

#### Description

Radial Artery Spasm

#### Timepoint

During Angiography

#### Method of measurement

Radial Vasospasm Scale

## Secondary outcomes

### 1

#### Description

Anxiety Score

#### Timepoint

Before relaxation intervention or pethidine injection and After angiography

#### Method of measurement

Beck Anxiety Inventory (BAI), Visual Analog Scale anxiety (VAS)

### 2

#### Description

Pain Severity

#### Timepoint

Before relaxation intervention or pethidine injection and After angiography

#### Method of measurement

Visual Analog Scale for pain

## Intervention groups

### 1

#### Description

Intervention group 1: It will be administrated 25 mg blouse Pethidine to the research samples by intravenous injection in half an hour before angiography.

#### Category

Treatment - Drugs

### 2

#### Description

intervention group 2: It will do Benson relaxation method for 15-20 minutes at half an hour before angiography. The patient will be requested to loose and relax his/her

muscles and while Breathing out of the nose and exhale through the mouth, repeat comforting words and think of other topics.

**Category**

Treatment - Other

**3****Description**

Control group: It will not do any intervention.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Baqiyatallah (AJ) Hospital

**Full name of responsible person**

Yasser Moazami Goodarzi

**Street address**

Nosrati Alley, South Sheykhbaheae St., Mollasadra St.,

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Alishiri

**Street address**

Nosrati Alley, South Sheykhbaheae St., Mollasadra St.,

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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**

Vice Chancellor for Research, Baqiyatallah University of Medical Sciences

**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**

Baqiyatallah Hospital

**Full name of responsible person**

Yasser Moazami Goudarzi

**Position**

Msc in Critical Care Nursing

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

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## 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*