

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### An investigation of local forearm heating on the pain intensity and hemorrhage of patients undergoing cardiac catheterization via radial artery at the time of withdrawal sheath: A pilot study

#### Protocol summary

##### Study aim

Determining of the effect of local forearm heating on the pain intensity and hemorrhage of patients Undergoing Cardiac Catheterization via Radial Artery at the Time of Withdrawal Sheath

##### Design

This study was designed as a phase 2 clinical trial with a control group of 50 patients in each group, in a double-blind, randomized manner, which CREATE A RANDOMISATION LIST program was used for randomization.

##### Settings and conduct

This study was conducted on 100 patients who are candidates for angiography and coronary angioplasty through the radial artery in the angiography department of Ayatollah Rouhani Hospital in Babol. For blinding, the sheaths were removed by people other than the present researcher and for data analysis, the studied groups were marked with alphabet labels.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65 years, indication of cardiac catheterization, non-emergency of cardiac catheterization. Exclusion criteria: history of previous catheterization through the radial artery, more than 3 catheter changes during the procedure, more than 3 attempts to puncture the artery

##### Intervention groups

In the intervention group, local heating of the hand with the Warm Touch device is performed for 3 minutes with hot air that has a temperature of 35-45 degrees centigrade from a distance of 20-30 cm. In the control group, the sheath is removed without any intervention.

##### Main outcome variables

Pain intensity; Bleeding

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220521054951N1**

Registration date: **2022-11-17, 1401/08/26**

Registration timing: **retrospective**

Last update: **2022-11-17, 1401/08/26**

Update count: **0**

##### Registration date

2022-11-17, 1401/08/26

##### Registrant information

##### Name

Atefeh Shamsian

##### Name of organization / entity

Shahid Rajaie Cardiovascular, Medical & Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3223 8301

##### Email address

shamsian1986@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-20, 1400/12/29

##### Expected recruitment end date

2022-06-21, 1401/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

An investigation of local forearm heating on the pain intensity and hemorrhage of patients undergoing cardiac catheterization via radial artery at the time of withdrawal sheath: A pilot study

**Public title**

An investigation of Local Forearm Heating on the Pain Intensity and hemorrhage of Patients Undergoing Cardiac Catheterization via Radial Artery at the Time of Withdrawal Sheath

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Ability and willingness to cooperate with the researcher ability to speak and understand Persian language age of 18 to 65 years indication of cardiac catheterization through the radial artery no emergency for cardiac catheterization no history of paralysis and hemiparesis no surgery on the hand no History of peripheral vascular diseases (diabetes) or peripheral neuropathy no mastectomy no vascular fistula in patients with kidney diseases

**Exclusion criteria:**

Patients who have undergone more than one radial artery catheterization patients who have had catheter replacement more than 3 times patients who have been punctured more than 3 times

**Age**

From **18 years** old to **65 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**

After block randomization with a size of 6, the patients are divided into two groups of 30 intervention and control (by CREATE A RANDOMISATION LIST computer program).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Shahid Rajaei Cardiology Research Training Center

**Street address**

Tehran - Wali Asr St. (Aj) - next to Mellat Park - Niayesh Corner of Shahid Rajaei Cardiovascular Training, Research and Treatment Center

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Approval date**

2022-07-15, 1401/04/24

**Ethics committee reference number**

IR.RHC.REC.1401.049

**Health conditions studied****1****Description of health condition studied**

Patients undergoing cardiac catheterization through the radial artery

**ICD-10 code**

Y84.0

**ICD-10 code description**

Cardiac catheterization as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

**Primary outcomes****1****Description**

Pain intensity

**Timepoint**

When leaving the sheet and an hour after that

**Method of measurement**

Visual analog scale

**Secondary outcomes****1****Description**

Hemorrhage

**Timepoint**

When leaving the sheet and an hour after that

**Method of measurement**

view

## Intervention groups

1

### Description

Intervention group: Local heating of the forearm for 3 minutes by the Warm Touch device, COVIDEN-2013), before removing the arterial sheath.

### Category

Treatment - Devices

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Babol Ayatollah Rouhani Hospital

#### Full name of responsible person

Seyed Atefeh Shamsian Khairabadi

#### Street address

Ayatollah Rouhani Hospital, Ganj Afrooz St.,  
Daneshgah Square, Babol

#### City

Babol

#### Province

Mazandaran

#### Postal code

47745-47176

#### Phone

+98 11 3222 9591

#### Email

Shamsian1986@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Mehdi Rajabnia

#### Street address

Babol University of Medical Sciences; Ganj Afrooz  
Street

#### City

Babol

#### Province

Mazandaran

#### Postal code

۴۷۱۷۶-۴۷۷۴۵

#### Phone

+98 11 3219 7667

#### Email

ramazan@yahoo.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Babol 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

Babol University of Medical Sciences

#### Full name of responsible person

Seyed Atefeh Shamsian Khairabadi

#### Position

student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

Ayatollah Rouhani Hospital, Ganj Afrooz St.,  
Daneshgah Square

#### City

Babol

#### Province

Mazandaran

#### Postal code

47745-47176

#### Phone

+98 11 3223 8302

#### Email

Shamsian1986@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Seyed Atefeh Shamsian Khairabadi

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

Ayatollah Rouhani Hospital, Ganj Afrooz St.,  
Daneshgah Square

#### City

Babol

#### Province

Mazandaran

#### Postal code

47745-47176

**Phone**

+98 11 3223 8305

**Email**

shamsian1986@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Seyyed Atefeh Shamsian Khairabadi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Ayatollah Rouhani Hospital, Ganj Afrooz St.,  
Daneshgah Square

**City**

Babol

**Province**

Mazandaran

**Postal code**

47745-47176

**Phone**

+98 11 3223 8305

**Email**

shamsian1986@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**

Not applicable

**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