

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of Manual versus Mechanical Compression methods in Hemostasis of Coronary Angiography via Snuff-Box Access

#### Protocol summary

##### Study aim

Comparison of two methods of homeostasis including manual compression and radial TR band in coronary angiography via snuff box method

##### Design

The clinical trial work consists of two parallel and single blinded non-randomized groups

##### Settings and conduct

Location: Shahid Chamran Heart Center, Isfahan, Iran. 80 patients under coronary angiography via snuff box method were divided into two equal groups of 40. In the first group hemostasis is performed through manual compression and in the second group using radial TR band.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for diagnostic coronary angiography, Written consent Exclusion criteria: Need to angioplasty, Unstable hemodynamic, acute myocardial infarction, severe renal failure, the sensory and motor deficits in the hands nerves, fracture of the bones wrist, Raynaud diseases, carpal tunnel syndrome, coagulation disorders

##### Intervention groups

To perform homeostasis, in first group, local compression is applied by hand and in second group, radial TR band is used.

##### Main outcome variables

homeostasis time; patient satisfaction; patient pain severity; hospitalization time; neuro-vascular complications.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181228042155N2**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **retrospective**

Last update: **2020-03-29, 1399/01/10**

Update count: **0**

##### Registration date

2020-03-29, 1399/01/10

##### Registrant information

###### Name

Mohammad Kermani-Alghoraishi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3345 9614

###### Email address

sm.kermani@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

2018-07-23, 1397/05/01

##### Actual recruitment end date

2019-12-22, 1398/10/01

##### Trial completion date

2020-01-21, 1398/11/01

##### Scientific title

Comparison of Manual versus Mechanical Compression methods in Hemostasis of Coronary Angiography via Snuff-Box Access

##### Public title

Homeostasis in angiography by snuff box method

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

candidate for diagnostic angiography and no need for angioplasty written consent

**Exclusion criteria:**

Unstable hemodynamics  
Acute myocardial infarction  
Severe renal failure (GFR <30)  
Fracture of the bones wrist  
Sensory and motor deficits in the hands nerves  
Raynaud diseases  
Capral tunnel syndrom  
Coagulation disorders  
Need to angioplasty

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **80**

Actual sample size reached: **74**

**Randomization (investigator's opinion)**

Not 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 Isfahan University of Medical Sciences

**Street address**

Hezar Jerib Street

**City**

Isgahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2020-03-04, 1398/12/14

**Ethics committee reference number**

IR.MUI.MED.REC.1398.658

**Health conditions studied**

**1**

**Description of health condition studied**

Methods of homeostasis in angiography through the snuff box artery

**ICD-10 code**

I25

**ICD-10 code description**

Chronic ischemic heart disease

**Primary outcomes**

**1**

**Description**

Determine of hemostasis time in coronary angiography via snuff box method

**Timepoint**

Just after the angiography

**Method of measurement**

Time (minute)

**Secondary outcomes**

**1**

**Description**

Mean of pain score

**Timepoint**

immediately,1 hour and 4 hours after angiography

**Method of measurement**

Visual Analuage Scale

**2**

**Description**

Neuro-vascular complications

**Timepoint**

During the hospitalization till 1 month after discharge

**Method of measurement**

Physical exam

**Intervention groups**

**1**

**Description**

Intervention group: In this intervention, hemostais is performed by using of local compression with hand in puncture site of snuff box artery. After passing 10 minute, the puncture site is checked foe hemostasis and the compression is done if needed. The first time of hemostasis is recorded as primary hemostasis time.

**Category**

Treatment - Other

**2**

**Description**

Intervention group: Intervention group: In this intervention, homeostasis is performed by using an inflatable air filled wrist bracelet named as TR band (manufactured by Lepu Medical Technology Co. Beijing, China) at the distal forearm and radial artery site. After passing 20 minute and every ten minute intervals, the

wrist bracelet air was reduced to evaluation of primary hemostasis. If needed, air is injected again inside the wrist bladder. The first time of hemostasis is recorded as primary hemostasis time

**Category**

Treatment - Devices

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

Shahid Chamran Heart Center

**Full name of responsible person**

Mohammad Kermani-Alghoraishi

**Street address**

Salman Farsi street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

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**Phone**

+98 31 3260 0961

**Email**

sm.kermani@med.mui.ac.ir

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Farshad Roghani-Dehkordi

**Street address**

Hezar Jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

roghani\_int@yahoo.com

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Farshad Roghani-Dehkordi

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**

Salman Farsi

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**Province**

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Kermani-Alghoraishi

**Position**

Assistance Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Kermani-Alghoraishi

**Position**

Assistance Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Non-identifiable patient data including patient information and analysis in journal publications or sending to academic researchers

**When the data will become available and for how long**

After publishing the article according to journal rules

**To whom data/document is available**

Academic Researchers

**Under which criteria data/document could be used**

For similar researches

**From where data/document is obtainable**

Corresponding authors

**What processes are involved for a request to access data/document**

Request to corresponding author email

**Comments**