

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of Three Methods of Hemostasis by Use of Ulnar TR Band, Manual Compression and Wrist Hyperextension in Patients Undergoing Coronary Angiography via Trans-Palmar Access

Protocol summary

Study aim

- Determine of hemostasis time in manual compression, ulnar TR band and wrist hyperextension methods in patients undergoing coronary angiography via palmar artery

Design

Three arm parallel groups, non-randomized with blinded outcome assessment.

Settings and conduct

Location: Chamran Heart Center, Isfahan, Iran. All patients candidate for coronary angiography with consent and notification were randomly divided into three groups of homeostatic control including local compression, ulnar TR band and wrist hyperextension; after coronary angiography done through palmar artery.

Participants/Inclusion and exclusion criteria

Inclusion: Candidate for coronary angiography. Exclusion: Needing angioplasty, Unstable hemodynamics and cardiogenic shock, Acute myocardial infarction, Coagulopathy and anti-coagulant, medication use with INR > 2.0, Severe renal failure (GFR <30) Raynaud disease, Carpal tunnel syndrome, The sensory and motor deficits in the hands nerve and the internal fracture of the bones wrist.

Intervention groups

First group: Palmar artery puncture site hemostasis with local compression Second group: Palmar artery puncture site hemostasis with ulnar TR band Third group: Palmar artery puncture site hemostasis with wrist hyperextension

Main outcome variables

Hemostasis time, pain severity of hemostasis site, patients satisfaction, hospitalization duration, complication occurrence.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200223046595N1**

Registration date: **2020-03-23, 1399/01/04**

Registration timing: **retrospective**

Last update: **2020-03-23, 1399/01/04**

Update count: **0**

Registration date

2020-03-23, 1399/01/04

Registrant information

Name

Roya Kasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3260 3106

Email address

roya_k1988@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2019-07-01, 1398/04/10

Actual recruitment start date

2017-07-01, 1396/04/10

Actual recruitment end date

2019-12-11, 1398/09/20

Trial completion date

2020-01-15, 1398/10/25

Scientific title

Comparison of Three Methods of Hemostasis by Use of Ulnar TR Band, Manual Compression and Wrist Hyperextension in Patients Undergoing Coronary Angiography via Trans-Palmar Access

Public title

Comparison of hemostasis in palmar angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who underwent diagnostic angiography through palmar artery approach

Exclusion criteria:

Need to angioplasty Unstable hemodynamics and cardiogenic shock Acute myocardial infarction Coagulopathy and anti-coagulant medication use with INR > 2.0 Severe renal failure (GFR <30) Raynaud disease Carpal tunnel syndrome The sensory and motor deficits in the hands nerve and the internal fracture of the bones wrist

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Actual sample size reached: **106**

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

Faculty of Medicine, Isfahan University of Medical Sciences

Street address

Hezar Jerib

City

Isfahn

Province

Isfahan

Postal code

8174673461

Approval date

2018-12-12, 1397/09/21

Ethics committee reference number

IR.MUI.MED.REC.1397.157

Health conditions studied

1

Description of health condition studied

Angiographic site hemostasis, Coronary artery diseases

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Hemostasis time

Timepoint

After palmar artery sheath removal until cession of bleeding

Method of measurement

Based on minute

Secondary outcomes

1

Description

Pain severity

Timepoint

During the hamostasis method

Method of measurement

Based on VAS scale

2

Description

Hospitalization duration

Timepoint

Procedure time to discharge

Method of measurement

Based on total days

3

Description

Patients satisfaction

Timepoint

During the hemostasis methods

Method of measurement

Questionnaire

4

Description

Complication occurrence

Timepoint

During the hospitalization to 1 month after the discharge

Method of measurement

Based on physical exam

Intervention groups

1

Description

Intervention group: Local compression on palmar artery puncture site and assessment of hemostasis time

Category

Treatment - Other

2

Description

Intervention group: Use of Ulnar TR band on ulnar artery site and assessment of hemostasis time

Category

Treatment - Devices

3

Description

Intervention group: Wrist hyperextension and assessment of hemostasis time

Category

Treatment - Other

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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

Roya Kasiri

Position

Cardiologist

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Latest degree

Subspecialist

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Not applicable

Title and more details about the data/document

Patients data and clinical outcomes will publish based on tables and paper

When the data will become available and for how long

After publication in the magazine and according to its magazine and publisher rules

To whom data/document is available

Researchers

Under which criteria data/document could be used

Clinical use

From where data/document is obtainable

Email

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

After publication, via email request to correspondence author and according to its magazine and publisher rules

Comments