

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of evidence based practice on outcomes after removal of arterial sheath in patients with angioplasty

Protocol summary

Summary

Objective: This study aimed to design and implement evidence-based care guidelines for removing arterial sheath in patients undergoing angioplasty of coronary artery. Patients and Methods: This clinical trial was performed in 200 patients (two groups of 100 patients; age 62.5 ± 10.8 years) from July 2014 to February 2014 in Baqiyatallah University of Medical Sciences (BUMS), Tehran, Iran. First, we designed a five-step guideline for removing the arterial sheath. Then the designed guideline in the current study and the routine guideline were used for removing the arterial sheath in patients in the intervention and the control groups, respectively. Finally, we recorded the effects and outcomes including bleeding, vasovagal, urine retention, and back pain. inclusion criteria: patient does not have hemodialysis – patients who do not require emergency percutaneous Transluminal coronary Angioplasty(PTCA) exclusion criteria: patients who for any reason had a sudden increase in serum creatine that were leading to hemodialysis patients who developed severe hemorrhage in the arterial sheath place and returned to cath lab.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604138650N8**

Registration date: **2016-06-05, 1395/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-05, 1395/03/16

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Baqiyatalla University of Medical sciences

Expected recruitment start date

2014-07-01, 1393/04/10

Expected recruitment end date

2015-01-30, 1393/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of evidence based practice on outcomes after removal of arterial sheath in patients with angioplasty

Public title

Outcomes of removal of arterial sheath in patients with angioplasty

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: 1- patient does not have hemodialysis
2-patients who do not require emergency percutaneous Transluminal coronary Angioplasty(PTCA) exclusion criteria: 1- patients who for any reason had a sudden increase in serum creatine that were leading to

hemodialysis 2- patients who developed severe hemorrhage in the arterial sheath place and returned to cath lab.

Age

From **42 years** old to **89 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The objectives of the study were explained to the patients and informed consent was obtained. Then according to the inclusion criteria, patients were randomly assigned based on random-number table to intervention (n =100) and control group (n=100). Then, in control group according to the conventional methods and in intervention group based on the new designed guideline, removal of the arterial sheath and then outcomes (vasovagal, bleeding, hematoma, urine retention and back pain) are recorded.

Secondary Ids

empty

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

Ethics committee of Baqiyatallah University of Medical sciences

Street address

6th Floor, Nursing Faculty, Baqiyatallah University of Medical Sciences, P.O.Box: 19575174

City

Tehran

Postal code

00982119575174

Approval date

2014-04-30, 1393/02/10

Ethics committee reference number

IR.BMSU.REC.34055904

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

Coronary Artery disease

ICD-10 code

I25

ICD-10 code description

ischemic heart disease

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

Vasovagal

Timepoint

During and after removal the arterial sheath

Method of measurement

check list

2**Description**

Bleeding

Timepoint

During and after removal the arterial sheath

Method of measurement

check list

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

Hematoma

Timepoint

After removal the arterial sheath

Method of measurement

Check list

2**Description**

Urine retention

Timepoint

After removal the arterial sheath

Method of measurement

Check list

3**Description**

Back pain

Timepoint

After removal the arterial sheath

Method of measurement

Check list

Intervention groups

1

Description

In the intervention group, removal of the arterial sheath and clinical care were based on the following protocol. 1. Control of ACT in the third hour after angioplasty 2. If ACT was less than or equal to 175, the arterial sheath would be removed by manual compression. 3. Put direct pressure on the arterial sheath insertion site for two to three minutes so that the dorsalis pedis pulse disappears. Then lower the pressure to feel the dorsalis pedis pulse. Continue pressuring until hemostasis (10 to 20 minutes). 4. Put pressure dressing on arterial sheath area by a trained doctor or nurse. 5. Put two sandbags (4 kg weight per bag) on the dressing by nurse 6. Remove the first and the second sandbags two and three hours after removing the arterial sheath, respectively. 7. Patients were out of bed three hours after removal of the arterial sheath in case of no complication. 8. Record outcomes of removal of the arterial sheath in the data record form (all outcomes during the removal and up to one day after that were recorded).

Category

Prevention

2

Description

In control patients, the arterial sheath was removed 4 to 6 hours after angioplasty, and then the manual compression was used for hemostasis. Two 8 kg sandbags compressed the dressing position. The first and second sandbags were removed two hours and 4-6 hours after removing the arterial sheath, respectively. Patients were out of bed 6 hours after removing the arterial sheath. Finally, outcomes of removing the arterial sheath, during this procedure and up to one day after that, were logged in the data record form.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital ,cardiac care unit

Full name of responsible person

Ali reza paraj

Street address

Baqiyatallah hospital,mollasadra Ave,Vanak Sq,Tehran,Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Afshin pakjoo

Street address

vice chancellor for research,Baqiyatallah University of Medical Sciences

City

Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

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

School of nursing, Baqiyatallah University of Medical Sciences, Tehran, Iran

Full name of responsible person

Ali reza paraj

Position

Master student of critical care nursing

Other areas of specialty/work

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Web page address**Person responsible for updating data****Contact****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