

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Influence of cannulation point during infraclavicular subclavicular vein catheterization in coronary artery bypass graft surgery

Protocol summary

Study aim

The aim of this study was to investigate the complications of Midpoint versus lateral approaches for subclavian vein catheterization during coronary artery bypass graft (CABG) surgery

Design

Two arm parallel group randomised clinical trial with blinded postoperative care and outcome assessment.

Settings and conduct

This study is a randomized clinical trial that is performed in Farshchian Heart hospital in hamadan. The patients were randomly assigned to one of the two groups (Midpoint or lateral approach for subclavian vein catheterization) of the trial using block randomization method (size of block = 4). The blindness of physician was not possible, Therefore, It is a Single blinded study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Four hundred and forty patients of aged between 25 and 89 years who schedule to undergo coronary artery bypass graft surgeries are enrolled for the study. Exclusion criteria: Previously thoracic surgery; Infection in catheterization site and emergency surgery

Intervention groups

After induction of anesthesia and tracheal intubation, The cannulations will done through Midpoint (Inserting the needle 2 to 3 cm inferior to the midpoint of the clavicle) or Lateral Approach (Inserting the needle 1 to 2 cm lateral to the midclavicular line) for subclavian vein catheterization.

Main outcome variables

Success of catheterization and Complications of subclavian vein catheterization: Malposition, subclavian artery puncture, Pneumothorax, Hematoma at puncture site.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120721010348N5**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Masoud Tarbiat

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-29, 1397/02/09

Expected recruitment end date

2018-10-31, 1397/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Influence of cannulation point during infraclavicular subclavicular vein catheterization in coronary artery bypass graft surgery

Public title
complications of subclavicular vein catheterization

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients of aged between 25 and 89 years who schedule to undergo coronary artery bypass graft surgeries are enrolled for the study.
Exclusion criteria:
Previously thoracic surgery; Infection in catheterization site
Emergency surgery

Age
From **25 years** old to **89 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **440**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were randomly assigned to one of the two groups (Lateral or Midpoint Approach for catheterization) of the trial using randomly blocks(size of block = 4)

Blinding (investigator's opinion)
Single blinded

Blinding description
All patients are randomized selected as L (lateral approach) or M (Midpoint approach) papers for catheterization. Outcome assessor and Data analyser only encounter with L or M papers.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Fahmedah street, Hamadan, Iran
City

Hamadan
Province
Hamadan
Postal code
08138381747
Approval date
2018-04-28, 1397/02/08
Ethics committee reference number
IR.UMSHA.REC.1397.35

Health conditions studied

1

Description of health condition studied
External causes of morbidity and mortality
ICD-10 code
Y70-Y82
ICD-10 code description
Medical devices associated with adverse incidents in diagnostic and therapeutic use

Primary outcomes

1

Description
Catheter malposition
Timepoint
One day after surgery
Method of measurement
Chest X- ray

Secondary outcomes

1

Description
Injury to subclavian artery
Timepoint
During catheterization
Method of measurement
Observation by physician

Intervention groups

1

Description
Control group: The catheter will be inserted in right subclavian vein through Midpoint approach.
Category
Prevention

2

Description
Intervention group: The catheter will be inserted in right subclavian vein through Lateral approach.
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

Street address

Vice Cbancellor for Research and Technology of Hamadan University of Medical Sciences, Hamadan University of Medical Sciences, Fahmideh Street, Hamadan, IRAN

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Grant name

Vice Cbancellor for Research and Technology of Hamadan University of Medical Sciences

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

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Masoud Tarbiat

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Hamadan

City

Hamadan

Province**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

Undecided - It is not yet known if there will be a plan to make this available

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