# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 catheterizetion 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 needle1 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, Pneomotorax, 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)
**Phone**
+98 81 1825 1244
**Email address**
masoud.tarbiat@umsha.ac.ir

**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 catheterizetion 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 apprqach) 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 subclavein vein through Midpoint approach.
**Category**
Prevention

**2**

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

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Farshchian Hospital

**Full name of responsible person**
Masoud Tarbiat

**Street address**
Hamadan University of Medical Sciences، Fahmideh Street، Hamedan, IRAN

**City**
Hamadan

**Province**
Hamadan

**Postal code**
38381742

**Phone**
+98 81 3820 1506

**Fax**
+98 81 3838 1742

**Email**
masoudtarbiat@gmail.com

**Web page address**
http://www.umsha.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Hamedan University of Medical Sciences

**Full name of responsible person**
Saeid Bashirian

**Street address**
Vice Cbanceller for Research and Technology of Hamadan University of Medical Sciences, Hamadan University of Medical Sciences، Fahmideh Street، Hamadan, IRAN

**City**
Hamadan

**Province**
Hamadan

**Postal code**
3831742

**Phone**
+98 81 3820 1506

**Fax**
+98 81 3838 1745

**Email**
mt_383@yahoo.com

**Web page address**
http://www.umsha.ac.ir

**Grant name**
Vice Cbanceller for Research and Technology of Hamedan 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

**Street address**
Nomber 293، West Block 22، Kashani Street، Hamadan

**City**
Hamadan

**Province**
Hamadan

**Postal code**
64517669644

**Phone**
+98 81 3820 1506

**Fax**
+98 81 1826 8034

**Email**
masoud.tarbiat@umsha.ac.ir

**Web page address**
http://www.umsha.ac.ir

## Person responsible for scientific 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
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**Phone**
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**Fax**
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**Email**
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**Web page address**
htpp://www.umsha.ac.ir

## Person responsible for updating data

**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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**Web page address**
http://www.umsha.ac.ir

## 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