# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Investigating the Effect of Implementing the Early Movement Protocol on the amount of Postoperative Bleeding in patients undergoing Open Heart Surgery

## Protocol summary

**Study aim**
Determining the Effect of Implementing the Early Movement Protocol on the amount of Postoperative Bleeding in patients undergoing Open Heart Surgery

**Design**
A clinical trial with a control group will be conducted on 92 patients with non-random allocation.

**Settings and conduct**
In the ICU Open Heart department of Imam Ali Hospital in Zahedan, patients after Open Heart Surgery will be brought from the patient's bed during the second day to implement the patient movement protocol, The patients will not know whether they will be in the intervention or control group.

**Participants/Inclusion and exclusion criteria**
Patients undergoing open heart surgery, With entry criteria including the Age range of 18 to 100 years, Getting a score of 19 and below from the Bleeding prediction questionnaire after Open Heart Surgery (people who will have moderate and severe risk), definite diagnosis The need for Open Heart Surgery, Undergoing CABG Heart Surgery, The ability to move (not having a disability or specific movement restriction after the operation), Extubation after 18 hours after the operation, Elective and non-emergency open heart surgery ؛ the conditions of not Entry into the study includes getting a score of 20 or higher on the Postoperative Bleeding questionnaire in Open Heart Surgery patients, Having an uncorrected coagulation disorder, Having a specific restriction of movement after the operation, Having severe uncontrollable bleeding, Stable Lack of hemodynamic status after surgery, Mechanical ventilation for more than 48 hours

**Intervention groups**
For the people in the intervention group, The Early Movement Protocol will be implemented so that they will be taken out of bed on the second day after the operation. The people of the control group will be taken out of bed according to the ward routine on the third day.

**Main outcome variables**
Blood drainage rate

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20231120060120N2**
Registration date: **2024-02-10, 1402/11/21**
Registration timing: **prospective**

Last update: **2024-02-10, 1402/11/21**
Update count: **0**

**Registration date**
2024-02-10, 1402/11/21

**Registrant information**

**Name**
Mahla Dahmardeh

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 54 3348 6610

**Email address**
mahla.dahmardeh.nurse1999@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-03-19, 1402/12/29

**Expected recruitment end date**
2024-09-20, 1403/06/30

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the Effect of Implementing the Early Movement Protocol on the amount of Postoperative Bleeding in patients undergoing Open Heart Surgery

**Public title**
Effect of Implementing the Early Movement Protocol on the amount of Postoperative Bleeding
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age range from 18 to 100 years Getting a score of 19 and below from the bleeding prediction questionnaire after open heart surgery (people who will have moderate and severe risk) Definitive diagnosis of the need for open heart surgery Undergoing CABG heart surgery The ability to move (not having a disability or restriction of specific movement after the operation) Extubation from 18 hours after the operation Elective and non-emergency open heart surgery
**Exclusion criteria:**
Getting a score of 20 or higher from the postoperative bleeding questionnaire in open heart surgery patients Having an uncorrected coagulation disorder Having a specific restriction of movement after the operation Having uncontrollable heavy bleeding Having severe changes in hemodynamic status Unstable hemodynamic status after surgery Mechanical ventilation for more than 48 hours
**Age**
From **18 years** old to **100 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **46**
**Randomization (investigator's opinion)**
Not randomized
**Randomization description**
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
The researcher will be present at the bedside of the patients, will explain to them the purpose of the study, and the informed consent form will be completed by the patients to participate in the study, but the people in the intervention and control groups will not know which group they will be in. Both groups will receive routine ward care. That is, they will be taken out of bed on the third day after the operation. The people of the intervention group will be taken out of bed on the second day to move, but they will not know that they will be part of the intervention group.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Zahedan University of Medical Sciences
**Street address**
Dr. Hasabi Square, Zahedan University of Medical Sciences
**City**
Zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
9816113876
**Approval date**
2023-12-24, 1402/10/03
**Ethics committee reference number**
IR.ZAUMS.REC.1402.391

## Health conditions studied

### 1

**Description of health condition studied**
Open Heart Surgery
**ICD-10 code**
T82.0
**ICD-10 code description**
Mechanical complication of heart valve prosthesis

## Primary outcomes

### 1

**Description**
Bleeding volume measured in Bottle Chest
**Timepoint**
The first, Second and Third days after Open Heart Surgery
**Method of measurement**
Blood volume and drainage measured in Bottle Chest

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: On the second day after open heart surgery, they will be taken out of bed to perform the movement protocol. Early movement will be done in such a way that first the patient will be placed in the bed in a semi-sitting position, he will be in this condition for 15 minutes, then he will return to the lying position. After one hour in bed, he will be in a sitting position, he will be in this position for 15 minutes, then he will return to the lying position. An hour later, he will be placed on the edge of the bed with his legs hanging for 15 minutes, then he will return to the lying position, after an hour he will sit on the side of the bed for 15 minutes and return to the bed again. An hour later, he will walk a few steps next to the bed and return to the bed again. All steps will be according to the patient's tolerance.

**Category**
Other

### 2

**Description**
Control group: On the third day, according to the department's routine, they will be taken out of bed to implement the movement protocol

**Category**
Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Imam Ali Hospital, Zahedan University of Medical Sciences

**Full name of responsible person**
Mahla Dahmardeh

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## Sponsors / Funding sources

### 1

**Sponsor**

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

**Full name of responsible person**
Mohsen Taheri

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info@zaums.ac.ir

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Zahedan University of Medical Sciences

**Proportion provided by this source**
80

**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**
Zahedan University of Medical Sciences

**Full name of responsible person**
Mahla Dahmardeh

**Position**
Student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available

**Title and more details about the data/document**
The data will be analyzed and the results will be presented in the article.

**When the data will become available and for how long**
Since 2024

**To whom data/document is available**
The data will be presented in the form of results in the article and researchers can access it

**Under which criteria data/document could be used**
The data will be presented in the form of results in the article and researchers can access it

**From where data/document is obtainable**
By sending an email to Mehla Dehmardeh, mahla.dahmardeh.nurse1999@gmail.com

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

**Comments**