

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of early showering after coronary artery bypass graft surgery on wound infection, pain and patient comfort.

Protocol summary

Study aim

To determine the effects of early showering after coronary artery bypass graft surgery on wound infection, pain and patient comfort

Design

A clinical trial with a control group, with parallel groups, one-sided blind, randomized, phase 2 on 88 patients. For randomization, block method is done with the help of randomization site.

Settings and conduct

This randomized controlled clinical trial will be conducted in the open heart surgery intensive care unit of Valiasr Faraja Hospital in Tehran in 1402. A written consent form is obtained from the patients who meet the entry requirements, and the intervention protocol is based on the Declaration of Helsinki. Patients are not blinded. The data analyst will not be aware of the allocation of patients to groups.

Participants/Inclusion and exclusion criteria

Age above 18 years; ability to speak Persian; perform CABG through median sternotomy and under cardiopulmonary pump; removal of chest tubes 48 to 72 hours after surgery. Exclusion criteria include cognitive disorders; physical disorders; prolongation of chest tube removal after 72 hours; need to return to the operating room.

Intervention groups

In the intervention group, bathing is done daily from 48 hours after the operation until the time of discharge, and after discharge it is done daily at home. The evaluations are done daily until the time of discharge and the last evaluation is done on the 14th day after the operation. In the control group, according to the hospital routine. Bathing is not done until discharge and the first bath at home is done daily. Assessments are daily until discharge and on the 14th day after surgery.

Main outcome variables

The percentage of wound infection through the operation site infection profile form, the pain score through the

visual analog scale, the comfort score through the visual analog scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230917059444N1**

Registration date: **2023-10-12, 1402/07/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-12, 1402/07/20**

Update count: **0**

Registration date

2023-10-12, 1402/07/20

Registrant information

Name

Mohsen Safarabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

mohsensafarabadi313@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-11, 1402/07/19

Expected recruitment end date

2024-03-09, 1402/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of early showering after coronary artery bypass graft surgery on wound infection, pain and patient comfort.

Public title

Effects of early showering after coronary artery bypass graft surgery on wound infection, pain and patient comfort.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age above 18 years Ability to speak Persian Performing CABG through median sternotomy and under cardiopulmonary pump Removal of chest tubes 48 to 72 hours after surgery

Exclusion criteria:

Cognitive disorders Physical disorders Prolonged exit of chest tubes after 72 hours Need to go back to the operating room In the data collection process, patients who develop postoperative complications such as cardiac tamponade, pleural effusion, or pneumonia, are transferred to another hospital, or require reoperation will be excluded.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomized into two groups: early shower and late shower. Patients are not blinded. The data analyst will not be aware of the allocation of patients to groups. The selection of samples will be continuous and the allocation of samples to two groups will be done using the website <https://www.sealedenvelope.com/>.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are not blinded. The data analyst will not be aware of the allocation of patients to groups. The infectious specialist will not be aware of the division of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahed University

Street address

At the beginning of Tehran-Qom freeway, in front of Imam Khomeini's shrine

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2023-09-10, 1402/06/19

Ethics committee reference number

IR.SHAHED.REC.1402.080

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

Effects of early showering after coronary artery bypass graft surgery on wound infection

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Effects of early showering on pain after coronary artery bypass graft surgery

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Effects of early showering after coronary artery bypass surgery on patient comfort

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Percentage of people with wound infection

Timepoint

Measurement of wound infection rate 48 hours after surgery and daily before showering until discharge and 14 days after surgery

Method of measurement

The profile of the incidence of surgical site infection

2

Description

Pain score on visual analog scale

Timepoint

Measuring the pain score 48 hours after the operation and daily after showering until discharge and on the 14th day after the operation

Method of measurement

Visual analog scale

3

Description

Patient comfort score on visual analog scale

Timepoint

Measuring the patient's comfort score 48 hours after the operation and daily after taking a shower until discharge and on the 14th day after the operation

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Preparation of culture from the nose to determine the carrier of nasal staphylococcus aureus before the operation, cutting the hair of the operation area and taking a shower before the operation, taking a written consent and completing the demographic information, dressing the wound with sterile gauze after the operation, Removal of chest tubes 48 to 72 hours after the operation by a nurse, performing a chest x-ray to check the possible complications of drain removal (such as pneumothorax) and evaluation by the surgeon, cleaning and disinfection of the bathroom environment by the service personnel, 4 to 6 hours later The wound dressings are removed from the exit of the chest tubes and while the place of exit of the chest tubes is covered with a waterproof dressing (of the same brand for all patients), Take a shower without rubbing or washing the wound strongly, with tap water, the total showering time will be 10 minutes, to maintain safety, patients sit on a chair and use the shower, to prevent hypothermia, the temperature of the bath is between 20 and 23 The temperature is maintained, for each patient, a separate slipper and a clean cover are used to throw on the chair, before going to the bathroom, vital signs and arterial blood oxygen saturation percentage of the patients are controlled, After bathing, do not get up suddenly from the chair, sit in a sitting position for at least 3 minutes, dry the body and the incision site with a sterilized towel, and the patient puts on his clothes, the waterproof dressing is removed from the place where the drains exit and The wound area is covered with antiseptic betadine

and then with sterile gauze and straw glue, The wound of the sternotomy area is kept clean and open with betadine, the wound of the graft removal area of the leg (saphenous vein outlet) is left and a varicose sock is worn. It is done up to 72 hours after the operation and then daily before showering. The first assessment of pain and comfort is done 48 to 72 hours after the operation and then daily 30 minutes after showering by the researcher. On the 14th day after the operation, the researcher comes to the clinic and evaluates pain and comfort, and the wound is evaluated for the possible occurrence of signs of infection on the same day in the clinic by an infectious specialist.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Faraja Hospital

Full name of responsible person

Mohsen Safarabadi

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Valiasr Hospital Faraja, More than four ways
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Shahriar Bijani

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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
Shahed University
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
Shahed University
Full name of responsible person
Mohsen Safarabadi
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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

