Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of silicone protective pad on pressure ulcers in patients undergoing coronary artery bypass

Protocol summary

Summary

This study is a double blind clinical trial to determine the effect of silicone protective pad on pressure ulcers in patients undergoing coronary artery bypass surgery. Criteria for inclusion included : 1.Age 75-30 years 2. Connect to pump circulation outside the body, Exclusion criteria included: 1. Long operation time more than 5 hours 2. emergency surgery. The sample size n = 82 for each group have been calculated. In the intervention group, of a silicone protective pad with length 90 width 60 thickness of 3.5 cm for pressure sores during the operation in the area of the sacrum and hips, which is the most common location of pressure ulcers,in hospital operating room Madani martyr in year 95- 94 will be used. The most important outcome of this study is to reduce the incidence of pressure ulcers in patients undergoing coronary artery bypass surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110619919N3**
Registration date: **2016-04-11, 1395/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-11, 1395/01/23

Registrant information

Name

Arefeh Davoodi Bavil Oliaii

Name of organization / entity

Nursing and Midwifery of Faculty, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 0648

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Recruitment status

Recruitment complete

Funding source

Research Center of Tabriz University of Medical Sciences

Expected recruitment start date

2016-01-22, 1394/11/02

Expected recruitment end date

2017-01-21, 1395/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of silicone protective pad on pressure ulcers in patients undergoing coronary artery bypass

Public title

The effect of silicone protective pad on pressure ulcer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in the study and signed an informed consent form; Age 75-30 years; Undergo bypass surgery for first time; No history of blood disorders; Having BMI 18.5 to 24.9; Connect to pump circulation outside the body; No history of bedsores. Exclusion criteria: Long operation time more than 5 hours; emergency surgery; Having skin problems such as hives, swelling, redness and sensitivity to drugs and environmental factors in the area of Batks; Having Sensorimotor disability[Such as stroke].

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The way of randomization is the blocking method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

University Street, University round, tabriz

City

Tabriz

Postal code

Approval date

2016-01-07, 1394/10/17

Ethics committee reference number

TBZMED.REC.1394.974

Health conditions studied

1

Description of health condition studied

Patients undergoing cardiac surgery

ICD-10 code

100-199

ICD-10 code description

120-125

Primary outcomes

1

Description

Reduce the incidence of pressure ulcers

Timepoint

Befor intervention, 24 and 48 hour after intervention and the time of discharge

Method of measurement

The measure Torrance Scale.

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group 1: In the intervention group, silicone protective pad with length of 90,width of 60 and a thickness of 3.5 cm for the prevention of pressure ulcers during surgery on the sacrum and hip area will be used.

Category

Prevention

2

Description

Cntrol group: The control group will not be any interference and these groups will receive the same care and routine Intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Afkham Vargaeei

Street address

University Street, University round, tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Tabriz University of Medical Sciences

Full name of responsible person

Dr. Rashidi Mohammad Reza

Street address

University street, University round,Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research,Tabriz 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 and Midwifery- University of Medical Sciences

Full name of responsible person

Aghal Moosa

Position

MSc student- Expert

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Faculty of Nursing and Midwifery, University of Medical Sciences

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Position

instructor, MSc

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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