

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Effect of Aloe Vera gel versus control group the severity of pain and improvement of lower limb ulcers in non-diabetic patients undergoing open-heart surgery: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of Aloe vera gel versus control group the severity of pain and improvement of lower limb ulcers in non-diabetic patients undergoing open-heart surgery

Design

This is a single-blind randomized clinical trial, phase II, in which the right and left sides of 35 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible diabetic patients undergoing open-heart surgery referring to the Chamran Hospital in Isfahan city during the study period will be enrolled in the trial and right and left sides of patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single-blinded so that the physician examining the patients will not be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 80 years, Open heart surgery, Preparing graft from saphenous veins on both legs, Exclusion criteria: Emergency open-heart surgery, Diabetes, Skin disease, Vascular disease, Sensitivity to Aloe vera, Chronic renal disease, Wound infection

Intervention groups

Intervention group: The surgical wound washing with normal saline and rubbing Aloe Vera gel and sterile dressing once a day for 5 days. Control group: The surgical wound washing with normal saline and sterile dressing once a day for 5 days.

Main outcome variables

The severity of surgical wound pain; the improvement of surgical wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N364**

Registration date: **2020-08-13, 1399/05/23**

Registration timing: **retrospective**

Last update: **2020-08-15, 1399/05/25**

Update count: **1**

Registration date

2020-08-13, 1399/05/23

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-06, 1398/06/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Aloe Vera gel versus control group the severity of pain and improvement of lower limb ulcers in non-diabetic patients undergoing open-heart surgery: a single-blind randomized clinical trial

Public title

Effect of Aloe Vera gel versus control group the severity of pain and improvement of lower limb ulcers in non-diabetic patients undergoing open-heart surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 80 years old Open heart surgery
Preparing graft from saphenous veins on both legs

Exclusion criteria:

Emergency open heart surgery, Diabetes, Skin disease, Vascular disease, Sensitivity to Aloevera, Chronic renal disease, Wound infection

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the right and left sides of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "right" on one sheet and "left" on another. Then, by referring to every patient, one of the sheets will be randomly taken. According to whether the sheet is taken right or left is assigned to the intervention group and the other side to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single-blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Isfahan University of Medical Sciences, Hezar Jarib Ave.

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Approval date

2018-12-06, 1397/09/15

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.452

Health conditions studied

1

Description of health condition studied

Surgical wound of saphenous veins

ICD-10 code

S75.2

ICD-10 code description

Injury of greater saphenous vein at hip and thigh level

Primary outcomes

1

Description

The severity of surgical wound pain

Timepoint

On the first, forth, seventh, and fourteenth days

Method of measurement

Using Visual Analog Scale (VAS)

2

Description

The improvement of surgical wound

Timepoint

On the first, forth, seventh, and fourteenth days

Method of measurement

Using Reeda Scoring tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The surgical wound washing with normal saline and rubbing Aloe Vera gel and sterile dressing once a day for 5 days.

Category

Treatment - Drugs

2**Description**

Control group: The surgical wound washing with normal saline and sterile dressing once a day for 5 days.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Chamran Hospital in Isfahan city

Full name of responsible person

Nahid Motamedi

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Chamran Hospital, Third Moshtagh Ave., Bozorgmehr Square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Nahid Motamedi

Position

Student of Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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

Data Dictionary

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