Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

A comparative study of the local effect of Aloe Vera gel with cold and warm compress on ecchymosis of the lower leg after coronary artery bypass surgery

Protocol summary

Study aim

Determining the local effect of aloe vera gel with hot and cold compresses on leg area hemorrhage of patients undergoing coronary artery bypass surgery

Design

A three-group controlled clinical trial with random allocation of 60 patients in phase 3, from among patients undergoing coronary artery bypass surgery and research units, with a gradual method based on the order of referrals, with random allocation (using a coin toss) in group A or group B or are controlled. Then, the samples in each group are randomly selected to determine the right or left leg for intervention, using two envelopes containing number 1 (intervention) and number 2 (control) inside a box, and based on the desired number, the cutting place Leg surgery patients are assigned to two intervention groups with aloe vera and control. The same procedure is done in groupB

Settings and conduct

Hospitalized patients chamran are placed in group A or B based on randomization

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed and written consent to participate in the study Coronary artery bypass surgery Vascular graft removal from both legs exclusion criteria: history of skin disease emergency surgery allergic to aloe vera using drugs or continuous use of alcohol or cigarettes history of vascular disease such as Raynaud's, Berger's, etc history of allergy coagulopathy or the need to take anti-coagulant drugs

Intervention groups

Steps of doing work in the intervention group is an aloe vera gel before dressing the wound for 6 days. In intervention group two, one of the legs is placed in a cold compress in the first 48 hours after the surgery, and then in the third to sixth days of the surgery, a warm compress is applied. In the intervention control group, routine wound cleaning and dressing are considered.

Main outcome variables

The average area of hemorrhage in A and B groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150715023216N16**
Registration date: **2023-11-06, 1402/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-06, 1402/08/15**
Update count: **0**

Registration date

2023-11-06, 1402/08/15

Registrant information

Name

Said Amini Rarani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3522 6158

Email address

ghadami@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the local effect of Aloe Vera gel with cold and warm compress on ecchymosis of the lower leg after coronary artery bypass surgery

Public title

A comparative study of the local effect of Aloe Vera gel with cold and warm compress on the lower leg after coronary artery bypass surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Informed and written consent to participate in the study Coronary bypass surgery removal of vascular grafts from both legs

Exclusion criteria:

history of skin disease emergency surgery allergy to aloe vera drug use or continuous alcohol or cigar use history of vascular disease such as Raynaud's, Berger's, etc. history of drug, food or allergy coagulopathy or the need to take anti-coagulant drugs

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The number of 60 patients who are candidates for coronary artery bypass surgery in Chamran Hospital according to the entry criteria, with a gradual method based on the order of referrals with random allocation (using a coin toss) in group A (local effect of aloe vera gel) or group B (use of cold and warm compresses) or control are placed. Then, the subjects in each group are randomly selected in order to determine the right or left leg for intervention, using two envelopes containing number 1 (intervention) and number 2 (control) inside a box, and based on the desired number, The surgical incision site of the patient's legs is allocated in the intervention leg with aloe vera and the control leg. The same procedure is done for the patient in group B. In groups A and B, one foot of the patient is treated and the other foot is considered as control.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hezarjerib street, Isfahan,Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2023-09-04, 1402/06/13

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.098

Health conditions studied

1

Description of health condition studied

Ecchymosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Average area of Ecchymosis

Timepoint

Days 2, 5, 7, 10 and 30 after coronary artery bypass surgery

Method of measurement

The program for determining the area of j image and A30s phone camera

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first stage of intervention in group A (local effect of aloe vera gel) is performed before

dressing the wound in the operating room. In the opposite leg, routine intervention is performed, i.e. washing the wound with normal saline and dressing with sterile gauze and adhesive and bandaging. This procedure continues for 6 days. Photographs are taken of the desired position (legs of both legs) (days 2, 5, 7, 10 and 30). On the 10th and 30th days, in the office of Dr. Mohsen Mir Mohammad Sadeghi, photographs of the patient's legs are taken and the area of hemorrhage is calculated using image j software.The aloe vera gel used in this research is prepared by Reyhan Naqsh Jahan Pharmaceutical Company based on the United States Pharmacopoeia (USP), which is packed in sterile containers under sterile conditions and in compliance with hygiene precautions with sterile gloves. Intervention with aloe vera gel in The first to sixth days are done in the inpatient departments. In group A, the first intervention stage is performed in the operating room by Dr. Mohsen Mir Mohammad Sadeghi's dedicated assistant with sterile aloe vera gel that has been prepared in advance on the affected leg, and then dressing is performed with sterile gauze, glue, and bandaging. Dressing with sterile gauze, glue and bandaging is performed on the control legThen, on a daily basis, standard methods of surgical wound care, such as washing with normal saline and performing sterile dressings once a day, elastic bandages for both legs of patients, are performed by nurses working in the special care and surgery department. Both groups A and B, one leg of the patient is treated and the other leg is considered as control.

Category

Prevention

2

Description

In group B (use of hot and cold compresses), one of the legs is placed under a cold compress in the first 48 hours after the surgery, and then on the third to sixth days of the surgery, a warm compress is applied, and in the opposite leg, a routine intervention, i.e. washing the wound with Normal saline serum and dressing is done with sterile gauze and adhesive and bandaging. This procedure continues for 6 days. Photographs are taken of the desired position (legs of both legs) (days 2, 5, 7, 10 and 30). On the 10th and 30th days, in the office of Dr. Mohsen Mir Mohammad Sadeghi, photographs are taken of the patient's legs and the area of hemorrhage is calculated using image j software.Intervention with cold compresses in the inpatient wards, on the first two days of surgery, a gel pack (HEPSUN) that has been placed in the freezer an hour before is placed around the wound with a gauze cover for 10 minutes, and in the next four days in the inpatient wards (Day 3, 4, 5, 6) A warm compress in the form of a jelly pack (HEPSUN) that we have previously placed in the microwave for one minute or in boiling water for 10 minutes, is placed in a cloth bag and placed around the wound on the control leg. Dressing is done with sterile gauze, glue and bandaging.On a daily basis, standard methods of surgical wound care, such as washing with normal saline and performing sterile dressings once a day, elastic bandages for both legs of patients are performed by nurses working in the special care and surgery department. Both groups A and B, one leg of the patient is treated and the other leg is considered as control.

Category

Prevention

3

Description

Control group: In this research, the control group is the same leg opposite to the intervention leg in intervention number 1 and 2. In both groups A and B, based on randomization, using a box, one leg of the intervention patient and the other leg It is considered as the control leg. In the control group, the routine intervention is washing the wound with normal saline and dressing with sterile gauze, glue and bandaging. This procedure continues for 6 days. Photographs are taken of the target position (legs of both legs) (days 2, 5, 7, 10 and 30) and the area of hemorrhage is calculated using image j software.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Chamran Hospital

Full name of responsible person
Ahmad Gadami

Street address
Hezarjerib Street . Isfahan .Iran

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 7583

Email
ghadami@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Ahmad Gadami

Street address
HezarJerib Street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8174673461
Phone
+98 31 3792 3028
Email
ghadami@mui.ac.ir

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
Ahmad Gadami
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
HezarJerib Street , Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7583
Email
ghadami@mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Shahriar Panah
Position
Student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
HezarJerib Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3028
Email
kosarhasan.shahryar06@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Shahriar Panah
Position
student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
HezarJerib Street , Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3028
Email
kosarhasan.shahryar06@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

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