

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the Local Effect of bovine ghee on complication after Angiography in Patients Under Coronary Angiography Admitted to Ali-ibn Abitaleb Hospital in Rafsanjan City in 2018-2019

Protocol summary

Study aim

Determination of the Local Effect of bovine ghee on complication after Angiography in Patients Under Coronary Angiography

Design

The intervention was divided into three groups with blind post-operative care and the results were randomly blocked

Settings and conduct

Patients for the coronary angiography (N=135) will be randomly divided to the control group and the two intervention groups. One hour before performing percutaneous angiography through the right femoral artery, intervention will be performed in groups, and every 12 hours will be repeated. Angiography location is checked at the first hour every 30 minutes and then at 2, 4, 6 and 10 hours after the angiography and the next day morning it will be controlled.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Performing angiography via femoral artery Lack of underlying illnesses Using Sheath 6 Not having known psychiatric disorders, fluency in Farsi and ability to communicate Their systolic blood pressure is less than 130 when withdrawal of arterial sheath Lack of ecchymosis, hematoma and hemorrhage in the angiography site Not taking steroids, heparin and enoxaparin Age more than 18 years old Exit criteria: Drug side effects History of localized allergy to animal oil The incidence of nonvascular complications of angiography Incidence of acute cardiac complications Any factor that causes the patient to get out of the reach of 48 hours

Intervention groups

In the first intervention group (Sheep oil), a gas impregnated with sheep's oil, and in the second intervention group (Cow oil) a gas impregnated with cattle oil. localized 10 x 10 cm in the groin is used in the

femoral artery. In the control group, Vaseline cream is used as a placebo in the same amount.

Main outcome variables

Study of the symptoms of hemorrhage and hematoma and ecchymosis by checklist in the studied groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180729040630N2**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

Registration date

2019-03-11, 1397/12/20

Registrant information

Name

Mohammad Ali Zakeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3429 2316

Email address

mazakeri@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Local Effect of bovine ghee on complication after Angiography in Patients Under Coronary Angiography Admitted to Ali-ibn Abitaleb Hospital in Rafsanjan City in 2018-2019

Public title

Local Effect of sheep ghee on complication after Angiography

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing coronary angioplasty Performing angiography via femoral artery Lack of heart failure Lack of COPD Lack of kidney failure Lack of severe valve disease Lack of liver failure Lack of Blood disorders Using Sheath 6 to access the artery pathway Not having known psychiatric disorders Fluency in Farsi and ability to communicate Systolic blood pressure is less than 130 Lack of ecchymosis in the angiography site Lack of hematoma in the angiography site Lack of hemorrhage in the angiography site Not taking steroids, heparin and enoxaparin Age more than 18 years old

Exclusion criteria:

Drug side effects History of localized allergy to animal oil The incidence of non-vascular complications of Angiography in the patient Types of cardiac dysrhythmia Contrast agents Cardiac tamponed Cerebrovascular accident (CVA) Pulmonary edema Cardio-respiratory arrest Decreased consciousness Angioplasty Emergency Surgery Lack of cooperation Personal satisfaction and discharge

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Random block

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind study. Participants and

researchers are unaware of the allocation of study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Bulvar, Rafsanjan.

City

Rafsangan

Province

Kerman

Postal code

7717933777

Approval date

2018-12-23, 1397/10/02

Ethics committee reference number

IR.RUMS.REC.1397.167

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

Complications after Angiography

ICD-10 code

D69.9

ICD-10 code description

Bleeding

Primary outcomes**1****Description**

complication after Angiography

Timepoint

Before and after intervention

Method of measurement

Christenson's guideline, Visual Satisfaction Scale of Patients, Visual Scale of Pain And Fatigue Assay Scale for Routine Patients

Secondary outcomes

1

Description

Satisfaction of Patients

Timepoint

Before and after intervention

Method of measurement

Visual Satisfaction Scale of Patients

2

Description

pain

Timepoint

Before and after intervention

Method of measurement

Visual analogue pain scale

Intervention groups

1

Description

Intervention group: Cow oil

Category

Treatment - Other

2

Description

Intervention group: Sheep oil

Category

Treatment - Other

3

Description

Control group: Vaseline cream

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rafsanjan University of Medical Sciences

Full name of responsible person

Hassan Pakdaman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsi zadeh

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Mohammad Ali Zakeri

Position

Master of Science (MSc) in Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

No more 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