

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Formulation and Evaluation of Nitroglycerin 6% Aloe Vera Gel for Angina

Protocol summary

Study aim

This study plan outlines the detailed methodology for conducting a clinical trial to evaluate the efficacy, safety, and usability of a nitroglycerin 6% aloe vera gel for the treatment of angina.

Design

Pragmatic, community based, parallel group, double blinded, randomized controlled trial. Total 144 patients will be enrolled. Patients who met our inclusion criteria will be randomized into two groups.

Settings and conduct

• CPEIC Multan, a tertiary care hospital specializing in cardiac care. • Muhammad Rehabilitation Centre, Multan

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Patient at least 25-60-year-old. • Patient with suspected s angina pectoris who undergo coronary angiography • Chest pain • Symptoms of chest pain • Breast feeding mothers • Intestinal angina • Hypertensive patient • Abdominal infarction • Pregnant female
Exclusion criteria: • severe myocardial infarction • Cardiogenic shock • Severe heart failure • Hypersensitive to medicine • Severe hypotension • Cardiac tamponade

Intervention groups

Participants will be assigned to two groups. Group 1 will be given 6% nitroglycerin aloe vera gel and group 2 will be given sublingual nitroglycerine

Main outcome variables

Primary Outcome: Reduction in pain, reduction in the frequency and severity of angina episodes, as measured by patient diaries and angina-specific questionnaires (e.g., the Seattle Angina Questionnaire) AND ECG: ST-Segment Changes Reduction in ischemic changes on ECG. Secondary outcome: Changes in breathing pattern, reduction in shortness of breath

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230202057310N9**

Registration date: **2024-11-21, 1403/09/01**

Registration timing: **prospective**

Last update: **2024-11-21, 1403/09/01**

Update count: **0**

Registration date

2024-11-21, 1403/09/01

Registrant information

Name

Imran Ahmad Khan

Name of organization / entity

Muhammad Nawaz Shareef University of Agriculture, Multan

Country

Pakistan

Phone

+92 333 6120602

Email address

imran.ahmad@mnsuam.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-01, 1403/09/11

Expected recruitment end date

2024-12-30, 1403/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and Evaluation of Nitroglycerin 6% Aloe Vera Gel for Angina

Public title

Nitroglycerin 6% Aloe Vera Gel for Angina

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient at least 25-60-year-old of both genders Patient with suspected angina pectoris who undergo coronary angiography Intestinal angina Hypertensive patient Chest pain Pregnant female Breast feeding mothers Symptoms of chest pain

Exclusion criteria:

Severe myocardial infarction Cardiogenic shock Severe heart failure Severe hypotension Hypersensitive to medicine Cardiac temponade

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

This randomization will be done by computer-generated numbers to ensure fairness. Medications will be given in numbered white boxes, each with a unique medication number. The treatment codes will be kept by the principal investigator.

Blinding (investigator's opinion)

Double blinded

Blinding description

Statistical analyser and outcome assessor will be kept blind so that the result obtained will be without biasness.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Institutional Ethical Committee of Muhammad Institute of Medical and Allied Sciences

Street address

Multan

City

MULTAN

Postal code

66000

Approval date

2024-09-11, 1403/06/21

Ethics committee reference number

MIMAS/08/26/Imran

Health conditions studied

1

Description of health condition studied

Angina pain

ICD-10 code

I20

ICD-10 code description

Angina pectoris

Primary outcomes

1

Description

Reduction in pain

Timepoint

Before and after treatment

Method of measurement

Numerical pain rating scale (NPRS)

2

Description

reduction in the frequency and severity of angina episodes

Timepoint

Before and after treatment

Method of measurement

Angina-specific questionnaires (e.g., the Seattle Angina Questionnaire)

3

Description

Reduction in ischemic changes on ECG

Timepoint

Before and after treatment

Method of measurement

ECG: ST-Segment Changes

Secondary outcomes

1

Description

Changes in breathing pattern

Timepoint

before and after treatment

Method of measurement

Breathing pattern

Intervention groups

1

Description

Intervention group: Group 1 will be given 6% nitroglycerin aloe vera gel. We will apply a measured dose of the nitroglycerin 6% aloe vera gel to the skin (e.g., chest or upper arms) once daily or during angina onset.

Category

Treatment - Drugs

2

Description

Control group: group 2 will be given sublingual nitroglycerine. Nitroglycerine (0.5mg) tab will be given sublingually

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

CPEIC Multan, a tertiary care hospital specializing in cardiac care.

Full name of responsible person

Dr. Inam Ur Rehman

Street address

Abdali Road

City

Multan

Postal code

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Phone

+92 333 6120602

Email

dr.inam977@gmail.com

Web page address

2

Recruitment center

Name of recruitment center

Muhammad Rehabilitation Centre, Multan

Full name of responsible person

Kashaf Khan Anjum Bhutta

Street address

Bosan Road Multan

City

Multan

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66000

Phone

+92 326 0107374

Email

kashafbhatta1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Muhammad Institute of Medical and Allied Sciences, Multan, Pakistan.

Full name of responsible person

Dr. Zahid Manzor

Street address

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kashafbhatta1@gmail.com

Grant name

Student Fund

Grant code / Reference number

MIMAS/10/06/IAK

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

Yes

Title of funding source

Muhammad Institute of Medical and Allied Sciences, Multan, Pakistan.

Proportion provided by this source

70

Public or private sector

Private

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

Muhammad Institute of Medical and Allied Sciences, Multan, Pakistan.

Full name of responsible person

Kashaf Khan Anjum Bhutta

Position

Lecturer

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Muhammad Nawaz Sharif University of Agriculture

Full name of responsible person

Imran Ahmad Khan

Position

Coordinator Department of Pharmacy

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Ph.D.

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Person responsible for updating data**Contact****Name of organization / entity**Muhammad Institute of Medical and Allied Sciences,
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Other areas of specialty/work

Physiotherapy

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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

N/A

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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