Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 faliure • Hypersensitive to medicine • Severe hypotension • Cardiac temponade

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

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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
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Abdali Road
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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
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66000
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kashafbhutta1@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
Multan
City
Punjab
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66000
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kashafbhutta1@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
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Other areas of specialty/work
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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
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