

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Biological and Pharmacological Activities Of Squalene, Potential Uses In Acute Myocardial Infarction

Protocol summary

Study aim

The main goal of this study is to investigate the effect of squalene on the improvement of clinical, laboratory and imaging symptoms in patients with acute heart failure due to acute myocardial infarction.

Design

Clinical trial with a control group, with a parallel group, randomized, on 88 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Patients with acute myocardial infarction who were admitted to Imam Reza Hospital randomly divided into two groups , receiving squalene drops in addition to routine treatments and a control group (only receiving treatment) routines). Also, treatment with squalene drops will be done 4 times a day with a dose of 5 drops each time for 5 days. Patients undergo hemodynamic, echocardiographic and necessary tests in the first 24 hours before starting the drug and then after 30 days.

Participants/Inclusion and exclusion criteria

The criteria for entering the study will be acute anterior myocardial infarction with an ejection fraction of less than 40%, who are admitted to Imam Reza Hospital. Patients with underlying kidney disease or underlying heart disease or a history of coronary bypass are excluded from the study.

Intervention groups

Patients with anterior acute myocardial infarction with EF less than 40% who receive squalene in addition to routine treatments are the intervention group and patients with anterior acute infarction with ejection fraction less than 40% who are studied as control group and only conventional drugs And they receive routine heart disease, they are the control group of the study.

Main outcome variables

Echocardiographic parameters such as: ejection fraction, abnormality of valve motion, diastolic failure, pulmonary artery pressure, and valvular insufficiency.
Hemodynamic parameters such as: initial blood

pressure, presence or absence of pulmonary rales, blood oxygen saturation percentage.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221021056258N1**

Registration date: **2022-11-13, 1401/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-13, 1401/08/22**

Update count: **0**

Registration date

2022-11-13, 1401/08/22

Registrant information

Name

Alireza Fazeli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2024-11-05, 1403/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Biological and Pharmacological Activities Of Squalene,Potential Uses In Acute Myocardial Infarction

Public title

Biological and Pharmacological Activities Of Squalene In Acute Myocardial Infarction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 18 to 80 years old Patients who have been diagnosed with ST segment elevation myocardial infarction and have undergone successful vascularization with angioplasty in the vessel related to the infarct. Ejection fraction less than forty percent in the field of acute Myocardial infarction

Exclusion criteria:

Ventricular arrhythmia Congenital heart disease Suspected or documented history of heart failure or decreased ejection fraction (EF) of the left ventricle CABG candidate patients or previous CABG history GFR less than 30 People with autoimmune diseases or connective tissue disease People with cancer Pregnant and lactating women Psychiatric patients and people who cannot complete the one-month clinical follow-up during the study.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the random sequence is generated using www.randomization.com. Then, based on the size of the research sample, a number of envelopes with aluminum wrappers (in order not to make the contents of the envelopes unclear) are prepared and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of patient sampling, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

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**

Ethics committee of Mashhad University of Medical Sciences

Street address

Imam reza hospital., Ahmadabad Blvd., Mashhad Town

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Razavi Khorasan

Postal code

5467534564

Approval date

2022-04-11, 1401/01/22

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.182

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

Acute myocardial infarction

ICD-10 code

I21.0

ICD-10 code description

ST elevation (STEMI) myocardial infarction of anterior wall

2**Description of health condition studied**

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

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

Ejection fraction

Timepoint

Patients undergo echocardiography in the first 24 hours before starting the drug and then after 30 days.

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Wall motion abnormality

Timepoint

Before starting the medicine and also thirty days after starting the medicine.

Method of measurement

Echocardiography

2

Description

Diastolic dysfunction

Timepoint

Before starting the medicine and also thirty days after starting the medicine.

Method of measurement

Echocardiography

3

Description

Pulmonary arterial pressure

Timepoint

Before starting the medicine and also thirty days after starting the medicine.

Method of measurement

Echocardiography

4

Description

Valvular Dysfunction

Timepoint

Before starting the medicine and also thirty days after starting the medicine.

Method of measurement

Echocardiography

5

Description

Laboratory factors such as complete blood cell count.

Timepoint

Before starting the drug and after thirty days from the start of the drug.

Method of measurement

Laboratory kit.

Intervention groups

1

Description

Intervention group: In addition to routine treatments, the group receiving squalene drops will receive sublingually and 4 times a day with a dose of 5 drops each time for 5 days. The concentration of the drug is ten milligrams per milliliter and with It is produced by the collaboration of Mashhad Faculty of Medical Sciences and professors of

pharmacy and chemical engineers of the Faculty of Basic Sciences of Ferdowsi University of Mashhad. Squalene extracted from vegetable oils is a non-toxic and biocompatible lipid that has various applications in the food and pharmaceutical industries. Also, this compound is a precursor of cholesterol and one of the natural components of human skin and protects it against radiation. So far, its anti-inflammatory, antioxidant and anti-tumor properties have been investigated and proven in animal studies, and no toxicity and or adverse effects have not been reported in animals.

Category

Treatment - Drugs

2

Description

Control group: Only recipients of routine treatments for acute myocardial infarction and heart failure.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza Hospital

Full name of responsible person

Alireza fazeli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Majid Ghayoor Mobarhan

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Alireza fazeli

Position

Cardiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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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