

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparing the effect of syzygium and cinchona ointments on enoxaparin injection pain intensity in acute coronary syndrome

Protocol summary

Study aim

Determination of the effect of syzygium and cinchona ointments on the severity of Pain Caused by enoxaparin In patients with acute coronary syndrome

Design

Randomized clinical trial with four groups and parallel

Settings and conduct

The present study is a quasi-experimental study with 140 patients in Farshchian heart hospital in Hamedan. In the first group, injections of the first day (6 am) and for the second time at 6 am, 80 mg of enoxaparin are injected without any additional intervention. The day before injection of anoxoparin from the gum The tape will be used at the 1 cm stance and will be used on the area of the dressing. After the desired time, the injection is carried out by the researcher, and the pain will be measured immediately. The third day, half an hour before the injection, Clove ointment and fourth day placebo will be used then the pain will be measured. The procedure in the second, third and fourth groups is exactly the same as in the first group, with the difference in the order of use of extracts and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI Between 25-19, Patient alertness and ability to analyze pain, The absence of uncontrolled coagulation disorders Exclusion criteria: Infection and inflammation in the skin of the target area, Having allergies to herbal medicines

Intervention groups

Intervention: In the intervention groups, before injection of enoxaparin, syzygium and cinchona ointments will be used and the severity of the pain will be evaluated at different intervals within three days. In the control group, no additional intervention will be performed.

Main outcome variables

Severity of pain caused by injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N21**

Registration date: **2019-04-17, 1398/01/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-17, 1398/01/28**

Update count: **0**

Registration date

2019-04-17, 1398/01/28

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of syzygium and cinchona ointments on enoxaparin injection pain intensity in acute coronary syndrome

Public title

Effect of syzygium and cinchona ointments on pain intensity

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

BMI Between 25-19 Patient alertness and ability to analyze pain The absence of uncontrolled coagulation disorders

Exclusion criteria:

Having allergies to herbal medicines Infection and inflammation in the skin of the target area

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to four groups of 35 people based on quadruple random permutation blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.UMSHA.REC.1397.655

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Pain intensity

Timepoint

Before and after intervention

Method of measurement

Visual analoge scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: : In the cinchona ointment group, half an hour before the injection of enoxaparin, the cinchona ointment will be applied to the injection site

Category

N/A

2

Description

Intervention group: In the syzygium ointment group, half an hour before the injection of enoxaparin, the syzygium ointment will be applied to the injection site.

Category

N/A

3

Description

Intervention group: In the placebo group, half an hour before the injection of enoxaparin, the placebo will be applied to the injection site

Category

N/A

4

Description

Control group: No special action will be taken

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian heart center

Full name of responsible person

Gholamhossein Falahinia

Street address

Shahid Fahmideh St., Farshchian heart center,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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Shahid Fahmideh St., Hamadan University of Medical
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Grant name

Grant code / Reference number

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

No

Title of funding source

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Gholamhossein Falahinia

Position

Instructore

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Gholamhossein Fallahinia

Position

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Latest degree

Master

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

ZahraTabatabaei

Position

Student

Latest degree

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Other areas of specialty/work

Nursery

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Phone

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

No - There is not 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