

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of EMLA cream on pain severity of enoxaparin sodium injection in patients with acute coronary syndrome

Protocol summary

Summary

Double-blind study with cross over design on 76 patients with acute coronary syndrome has done to evaluate the effect of application of EMLA cream on Enoxaparin sodium injection pain severity. Inclusion criteria: Having consent for participation in the study; being oriented to person, place and time; Having at least reading and writing ability; have no Associated diseases that can affect patient pain assessment (delirium, dementia or severe depression, severe visual and hearing impairment, moderate to severe diabetic neuropathy); Be able to speak in Persian. Exclusion criteria: don't have willingness for participation in the study; having a continuous infusion of sedative medication such as: Midazolam; receiving of palliative drugs 2 hours before the injection. in the first day enoxaparin injection was performed for patients in the morning and evening in a usual way by research partner. In the second and third days, in the morning and evening EMLA cream and placebo crossoverly,two times a day, has applied for 60 min before injection. after passing 60 min, site has prepared and injection has done and pain severity has measured by Numerical Rating Scale(NRS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012112212N1**

Registration date: **2013-03-18, 1391/12/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-18, 1391/12/28

Registrant information

Name

Ali Asghar jesmi

Name of organization / entity

Mashhad university of Medical Science (MUMS)

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 1511

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Recruitment status

Recruitment complete

Funding source

Mashhad university of Medical Science (MUMS)

Expected recruitment start date

2012-09-27, 1391/07/06

Expected recruitment end date

2012-11-15, 1391/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of EMLA cream on pain severity of enoxaparin sodium injection in patients with acute coronary syndrome

Public title

The effect of EMLA cream on pain severity of enoxaparin sodium injection

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Having consent for participation in the study:being informed to person, place and time! Having the least reading and writing ability! haven't Associated diseases that can affect patient pain assessment

(delirium, dementia or severe depression, severe visual and hearing impairment, moderate-to-severe diabetic neuropathy) :Be able to speak the Persian language. Exclusion criteria: Having any tendency for participation to the study: having a noncontinuous infusion of sedative medication such as: Midazolam: receiving of palliative drugs 2 hours before the injection.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Science (MUMS)

Street address

doctora cross road. college of nursing and midwifery

City

Mashhad

Postal code

9137913199

Approval date

2012-06-14, 1391/03/25

Ethics committee reference number

5111928

Health conditions studied

1

Description of health condition studied

Angina pectoris

ICD-10 code

I20

ICD-10 code description

Angina pectoris

2

Description of health condition studied

Acute myocardial infarction

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

injection pain severity

Timepoint

60 min

Method of measurement

numerical rating scale (NRS)

Secondary outcomes

1

Description

fatigue

Timepoint

exactly before the injection

Method of measurement

fatigue siverity measurement visual scale

Intervention groups

1

Description

EMLA cream, 5mg tube , 1 gr ,60 min befor injection ,application 2inches of priumbilical area(overally two grams second and theird days of study) 2inches of priumbilical area.

Category

Treatment - Drugs

2

Description

almond hand and face cream, Made in iran,1 gr each times 60 min before injection(overally two grams second and theird days of study) 2inches of priumbilical area

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem center

Full name of responsible person

Ali Asghar Jesmi

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Taghi Abad squer, Mashhad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Science(MUMS)

Full name of responsible person

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College of Nurding and Midwifery, Doctora sq

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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 Science(MUMS)

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of medical science (MUMS)

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MSc candidate

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty*

