Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Comparison of Ofsar ointment and EMLA (procaine+lidocaine) ointment in local analgesia for access to vein in cardiac surgery patients before induction of anesthesia

Protocol summary

Summary

In open heart surgery for coronary artery bypass grafting, it requires the patient have not been any stress and pain until surgery. Venipuncture procedure is one of the processes that can cause pain before the surgery for patients. In order to prevent this pain, is applied local anesthetics especially combination of Prilocaine and lidocaine in EMLA cream format. Wormwood (apsinthion) has also been shown to have similar effects with this ointment that is comparison in this study (Phase I) between EMLA classical ointments with composition wormwood (apsinthion). In animal studies it has been done successfully and without complications. The study included 40 patients which are divided into two groups. For each patient have one gray angiocatheter with EMLA on hand and another gray angiocath with wormwood (apsinthion) on the other patient hand, the pain and hemodynamic changes and complications are compared. The study was double-blind and randomized. Inclusion criteria: All patients undergoing open heart surgery, coronary artery in Ekbatan center in Hamadan, elective surgery, patients between 18 to 75 years. Exclusion criteria: patient dissatisfaction, perform venipuncture on unconventional path, sensory and neurological disorders in the upper limbs

General information

Acronym
ofsar ointment

IRCT registration information
IRCT registration number: **IRCT2013120715696N1**
Registration date: **2014-01-10, 1392/10/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date
2014-01-10, 1392/10/20

Registrant information

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Hamedan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research and technology, Hamedan University of Medical Sciences

Expected recruitment start date
2014-01-21, 1392/11/01

Expected recruitment end date
2014-05-22, 1393/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Ofsar ointment and EMLA (procaine+lidocaine) ointment in local analgesia for access to vein in cardiac surgery patients before induction of anesthesia

Public title
Assessment efficacy and complications of OFSAR

Wormwood (apsinthion)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : all patients undergoing open heart surgery, coronary artery in Ekbatan center in Hamadan; elective surgery; patients aged between 18 to 75 years old. Exclusion criteria: patient dissatisfaction; perform venipuncture on unconventional path; sensory and neurological disorders in the upper limbs.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Control group and intervention group are the same. One of the upper limbs are for control group and the other for intervention group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Scienses

Street address

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Postal code

65178

Approval date

2013-05-01, 1392/02/11

Ethics committee reference number

275/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied

CABG: coronery arthery bypass grapht

ICD-10 code

121

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

Painless effect

Timepoint

40 minute befor Producer

Method of measurement

VAS index

Secondary outcomes

1

Description

Complication

Timepoint

24 hours after producer

Method of measurement

Check list

Intervention groups

1

Description

Intervention group on one hand with ofsar ointment

Category

Treatment - Drugs

2

Description

control group on other hand with EMLA ointment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ekbatan hospital

Full name of responsible person

Afshin Farhanchi

Street address

Taleghani street

City

Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Bashirian
Street address
Hamedan University of Medical Sciences, Mahdieh street
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
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

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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
Data Dictionary
empty