Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Comparison of two topical piroxicam and EMLA cream on fistula cannulation pain in hemodialysis patient

Protocol summary

Summary

Hemodialysis is the most common alternative therapeutic in patients with renal failure, which is used in Iran and the world. Widespread access to dialysis makes the lives hundreds of thousands patients with end-stage renal disease(ESRD) has longed.This process leads to repeated stress and pain to fistula cannulation. If can relieve this pain, improve treatment compliance and improve the quality of life in patients. The purpose of this study was to determine the effectiveness of two topical piroxicam and EMLA cream on fistula cannulation pain on hemodialysis patients. Study is trial, randomized, double-blind, controlled with placebo. The sample consisted of 75 dialysis patients (not suffering from psychological problems, addiction, chronic and acute pain or etc) with stratified method by age, gender, educational level and duration of fistula are blocking three Group A (piroxicam group), B (group EMLA cream) and C (control group) with equal numbers. In the first session of dialysis fistula cannulation procedure done without any interference and pain with using the VAS scale recorded. At the end of this session ,ointment tube that surface is covered with a transparent dressing disposal to patients. In the second session (next sessions of dialysis) for an hour before coming to the hospital, the patient rubbed ointment, covered with a transparent dressing and then cannulation is performed in the usual way and the pain is recorded. If unsuccessful on the first attempt and repeated needle cannulation of the skin, patient are excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051213301N1**
Registration date: **2013-05-24, 1392/03/03**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-05-24, 1392/03/03

Registrant information

Name
Mahdi Mohseni
Name of organization / entity
Lorestan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2013-04-25, 1392/02/05

Expected recruitment end date

2013-05-26, 1392/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two topical piroxicam and EMLA cream on fistula cannulation pain in hemodialysis patient

Public title

Comparison of two topical piroxicam and EMLA cream on fistula cannulation pain in hemodialysis patient

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: 1. The patient is willing to cooperate and participate in the research. 2. The patient has given informed consent to participate in research. 3. Age is between 18-80 years old. 4. Starting hemodialysis at lease 3 months before. 5. Patients don’t have verbal disability, mental and vision problems. 6. Patients don’t have prior history of mental illness or psychiatric hospitalization. 7. The patient is not addict. 8. The patient has no pain medication dependency. 9. The patient has no pain before cannulation. 10. The patient has not used sedative drugs in the last 24 hours of cannulation . 11. The fistula skin is not injured. 12. Patients don’t have history of G6PD, congenital or idiopathic Methemoglobinemia, liver disease, asthma, skin allergies, dermatitis, rash, thrombophlebitis, gastrointestinal bleeding. 13. Patients don’t have sensitivity to local anesthetic drugs, nonsteroidal anti-inflammatory drugs and other medicines. 14. Patients not be treated with sulfonamide drugs, nitrates and phenobarbital. Exclusion criteria: 1. Patient does not wish to continue research. 2. The patient is referred to another center. 3. If unsuccessful on the first attempt and repeated cannulation needle into the skin.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Lorestan University of Medical Sciences Ethics Committee
Street address
Lorestan University of Medical Sciences and Health Services, Research, Ethics Committee.
City
Khorramabad
Postal code
381351698
Approval date
2013-04-22, 1392/02/02
Ethics committee reference number
20084258

Health conditions studied

1

Description of health condition studied
Acute Pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
the pain of fistula cannulation
Timepoint
firstly without interference - the second after intervention
Method of measurement
visual pain scale

Secondary outcomes

1

Description
Short-term effects of topical drugs (piroxicam, EMLA cream and ointment A + D)
Timepoint
one hour after the drug
Method of measurement
observed effects

Intervention groups

1

Description
Group A or Group piroxicam in the first session dialysis procedure and without any interference cannulation performed at the second session an hour before cannulation of 2 g of piroxicam in fistula rubbed with gauze transparent is covered.
Category
Treatment - Drugs

2

Description
Group B or Group ointment Spelling: In the first session dialysis procedure and without any interference

cannulation performed at the second session an hour before cannulation of 2 g of ointment spelling fistula rubbed with gauze transparent is covered.

Category

Treatment - Drugs

3

Description

Group C or placebo in the first session dialysis procedure and without any interference cannulation performed at the second session an hour before cannulation of 2 g of ointment A + D in fistula rubbed with gauze transparent is covered.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital in Khorramabad

Full name of responsible person

Mehdi Mohseni

Street address

Revolution Street, Shohada Hospital

City

Khorramabad.

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University of Medical Sciences, Research

Full name of responsible person

Dr. Mohamed Hassan Kaydy

Street address

Lorestan University of Medical Sciences and Health Services, Research.

City

Khorramabad.

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Lorestan University of Medical Sciences, Research

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

Lorestan University of Medical Sciences

Full name of responsible person

Mehdi Mohseni

Position

Masters student in nursing

Other areas of specialty/work

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PhD student Nursing

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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