Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of Lidocaine ointment and Xylocain Spray on reducing the pain of Fistulas needles in Hemodialysis Patients

Protocol summary

Summary

The aim of this study is to compare two pain relief methods of lidocaine ointment and xylocaine spray to reduce the pain of the fistulas needles in hemodialysis patients. For this purpose, a double blind experimental study is conduced on 50 hemodialysis patients. Each time two needles are set aside for each patient; one is placed for the intervention and one for the placebo (vitamin D) In the ointment groups before injecting the needle, we will use 10 mg of lidocaine ointment or two puffs of xylocaine spray. In the other needle place a placebo will be used. Finally, after 10 minutes the pain level will be determined by visual analog scale. All of the needles will be of the same material and size.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060615965N2**
Registration date: **2015-12-17, 1394/09/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-17, 1394/09/26

Registrant information

Name

Majid Kazemi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 7663

Email address

dr.kazemi.n@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2014-04-30, 1393/02/10

Expected recruitment end date

2014-10-02, 1393/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Lidocaine ointment and Xylocain Spray on reducing the pain of Fistulas needles in Hemodialysis Patients

Public title

Comparison of the effects of Lidocaine ointment and Xylocain Spray on reducing the pain of Fistulas needles in Hemodialysis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients without extensive skin; local infection disorders Exclusion criteria: no consent

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **47**

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
Rafsanjan University of Medical science

Street address
Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan

City
Rafsanjan

Postal code
Iran

Approval date
2014-10-06, 1393/07/14

Ethics committee reference number
ir.rums.ac.8

Health conditions studied

1

Description of health condition studied
Chronic renal failure

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Pain

Timepoint
Immediately after entering stick

Method of measurement
Based on a numerical scale VAS

Secondary outcomes

empty

Intervention groups

1

Description
This study will be a crossover study. In the first instance one place of the Venipuncture will be used as a test and two puffs of xylocaine spray and in the other place the placebo (water) will be used. After ten minutes, pain at the site by another person (nurse) using a visual analog scale pain will be examined.

Category
Treatment - Drugs

2

Description
On the second time one place of the Venipuncture will be used as a test and 10 mg lidocaine ointment will be applied and in the other place a placebo (A+D ointment) will be used. After ten minutes, pain at the site using a visual analog scale pain will be investigated by another person (nurse).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ibn Abi Talib Hospital, Rafsanjan

Full name of responsible person
Dr.Majid Kazemi

Street address
Faculty of Nursing and midwifery, Rafsanjan

City
Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Dr. Majid Kazemi

Street address
Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan

City
Rafsanjan

Grant name

Grant code / Reference number

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

Title of funding source
Rafsanjan 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

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Majid Kazemi

Position

Phd

Other areas of specialty/work

Street address

Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan

City

Rafsanjan

Postal code

Phone

+98 34 3425 5900

Fax

Email

dr.kazemi.n@rums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Majid Kazemi

Position

Phd

Other areas of specialty/work

Street address

Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan

City

Rafsanjan

Postal code

Phone

+98 34 3425 5900

Fax

Email

dr.kazemi.n@rums.ac.ir

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

Data Dictionary

empty