

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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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 conducted 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.

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

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

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+98 34 3425 7663

Email address

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

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Rafsanjan University of Medical Sciences, Imam Ali
Boulevard, Rafsanjan

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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

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

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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***Data Dictionary***empty*