

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of EMLA Cream, Lidocaine spray and Ice bag on pain during intravenous cannulation in Hemodialysis Patients

Protocol summary

Summary

This clinical trial will be conducted on a group of 40 patients with arteriovenous fistula in Dialysis Ward of Shahid Rahnemoon Hospital in Yazd. The aim of this study is to compare three pain relief methods of lidocaine spray, EMLA cream and Ice bag to reduce the pain of the fistulas needles in hemodialysis patients. This study will be conducted as a Crossover design. forty hemodialysis patients of hemodialysis ward who are eligible are selected and Three interventions including EMLA Cream, Lidocain spray and Ice bag are performed for any patient in sequential sessions of hemodialysis with randomly assignment before inserting the needle into the fistula site. The exclusion criteria are: cold intolerance, allergy to lidocaine constituents and peripheral vessels damage. Interventions will include the use of ice bag for 5 minutes before inserting the needle into the fistula site, 2 puffs of lidocaine 5 minutes before inserting the needle into the fistula site and application of EMLA cream 20 minutes before inserting the needle into the fistula site. The dependent variable is pain on needle insertion into the arteriovenous fistula which will be studied using visual analogue Scale. At first, the acuity of pain on needle insertion into fistula is measured for each patient 2 minutes after insertion at three different times without any therapeutic intervention. Then, the pain acuity on needle insertion will be measured for each patient 3 times (totally 9 times) for each of the three intervention modalities using the visual analogue scale 2 minutes after needle insertion. Next, the data would be analyzed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102224655N1**

Registration date: **2016-02-06, 1394/11/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-06, 1394/11/17

Registrant information

Name

Samaneh Mirzaei

Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3525 7672

Email address

mirzaeis@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd University Of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of EMLA Cream, Lidocaine spray and Ice bag on pain during intravenous cannulation in Hemodialysis Patients

Public title

The effect of EMLA Cream, Lidocaine spray and Ice bag on pain intensity during insertion of vascular needles in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: History of at least three months of hemodialysis through fistula and lack of any problem in accessing vessels
Exclusion criteria: Cold intolerance, allergy to lidocaine constituents and peripheral vessels damage

Age

From **15 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

In Front of the Infertility Center, Safaieh street, Bu Ali Boulevard

City

Yazd

Postal code

Approval date

2015-09-27, 1394/07/05

Ethics committee reference number

ir.ssu.rec.1394.85

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z49.0

ICD-10 code description

Preparatory Care For Dialysis

Primary outcomes

1

Description

Pain

Timepoint

2 minutes after insertion the needle into the fistula site

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention: The application of EMLA Cream 5% (Contains 25 mg/g of Lidocaine and 25 mg/g of Prilocaine) 20 minutes before inserting the needle into the fistula site

Category

Treatment - Drugs

2

Description

Second intervention: The use of ice bag for 5 minutes before inserting the needle into the fistula site

Category

Other

3

Description

Third intervention: The application 2 puffs of lidocaine 10% spray (each puff include 10 mg lidocaine) 5 minutes before inserting the needle into the fistula site

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahnemoun Hospital of Yazd

Full name of responsible person

Samaneh Mirzaei

Street address

Shahid Rahnemoun Hospital, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Yazd University of Medical Sciences

Full name of responsible person

Dr Mostafa Javadi

Street address

In Front of the Infertility Center, Safaieh street, Bu Ali Boulevard

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Yazd 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**Name of organization / entity**

Yazd School of Nursing and Midwifery

Full name of responsible person

Samaneh Mirzaei

Position

Msn in Critical Care Nursing

Other areas of specialty/work**Street address**

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Full name of responsible person

Dr Mostafa Javadi

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Phd In Nursing

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Full name of responsible person

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Position

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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

