Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

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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
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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*