# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

26 Oct 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**

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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**
Msn in Critical Care Nursing
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*