Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the efficacy of the use of lidocaine gel with lidocaine spry and the use of pin needles in relieving the pain of needles for hemodialysis in children

Protocol summary

Summary

Objective: The objective is to compare the efficacy of using lidocaine gel, lidocaine spry and pin needles in relieving the pain of hemodialysis needles in children. This study will be performed on 20 dialysis patients who will complete an informed consent form in Dr. Sheikh hospital of Mashhad. First, using the common method for hemodialysis, the patient will be connected to the device using needles set, and pain intensity of needle injection will be recorded based on Visual Analog Scale (VAS) checklist. After three times of dialysis, intervention will start. At first, lidocaine spray for local anesthesia will be used for all patients, and the pain will be measured. Next time, a week later, lidocaine cream (EMLA cream) will be used and the pain will be measured over three dialysis sessions. And in the last week, the sheet of pin needles will be used. The oval-shaped devices of 60 * 80 mm size which contain multiple needles (6 pins /cm2) will be put around fistula of patient, and pressure is applied for 10 seconds. Then the pain questionnaire will be completed. Finally, the degree of pain relief resulted by each of the three methods will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610247892N6**
Registration date: **2017-03-13, 1395/12/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-13, 1395/12/23

Registrant information

Name

Anoosh Azarfar

Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 51 1606 1227

Email address

azarfara@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of the use of lidocaine gel with lidocaine spry and the use of pin needles in relieving the pain of needles for hemodialysis in children

Public title

Clinical trial in comparison of the efficacy of the use of lidocaine gel with lidocaine spry and the use of pin needles in relieving the pain of needles for hemodialysis in children

Purpose

Health service research

Inclusion/Exclusion criteria
Inclusion criteria: All patients undergoing hemodialysis of Children's Hospital; Informed consent; lack of previous sensitivity to lidocaine and spraying ointment. Exclusion criteria: unwillingness to continue cooperation; the incidence of drug sensitivity to ointments.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi),Daneshgah 16, Daneshgah Street
City
Mashhad
Postal code
Approval date
2016-12-28, 1395/10/08
Ethics committee reference number
IR.MUMS.fm.REC.1394.368

Health conditions studied

1

Description of health condition studied
Degree of pain relief in hemodialysis
ICD-10 code
Z49.0
ICD-10 code description
Preparatory care for dialysis

Primary outcomes

1

Description
Degree of pain during needle for hemodialysis
Timepoint
When needling in each session for hemodialysis
Method of measurement
Pain Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: using lidocaine spry for local anesthesia at first week of hemodialysis, next week lidocaine cream and the last week the page containing pin needles
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Dr.Sheikh Hospital
Full name of responsible person
Anoosh Azarfar, Associated professor, Subspecialist in children's nephrology
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Anoosh Azarfar
Position
Associated professor, subspecialist in children's nephrology
Other areas of specialty/work
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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