

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 spray 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

City

Mashhad

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Web page address**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**Street address**

Dr. Sheikh Hospital, Tohid Square, Motahari Avenue

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Full name of responsible person

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Position

Subspecialist in children's nephrology

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Position

Subspecialist in children's nephrology

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

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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