Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The comparison of effect of hugo point ice massage with 2% lidocaine gel on puncture- relted pain of fistula in hemodialysis patients.

Protocol summary

Summary

The purpose of this study is comparsion the effect of lidocaine gel 2% and hugo point ice massage on pain intensity of arteriovenous fistula puncture in heamodialysis patients.This study in patient treated hemodialys by arteriovenous fistula in fatemeh zahra and emam khomeiny hospital in sari. This study is a randomized clinical trial in which 74 patients heamodialysis randomly allocated to two groups of experiment to 2% lidocaine gel and experiment hugo point ice massage. Inclusion criteria: no pain whole body before insert of needle in to fistule exclusion criteria: no disease of preferal vascular and neuropathy: no known history of depression: starting hemodialysis for at least 3 months. Exclusion criteria: known allergies or sensitivities to lidocaine gel 2%: need to try for more of once: cognitive disorders: drug abuse 3 h before insert of needle in to fistule. First pain intersity of puncture measure without any intervention after needle insertion in arteriovenous fistula.then, during the next session hemodialys in the intervention group lidocaine gel, gel the amount 2 gr to extent 5 cm2, 12 minute befor AVF puncture was applied. during the next session hemodialys at group hugo point ice massege with ice cubes 2*2*2 cm2 at the 10 minute before arteriovenous fistula puncture massage on rotating web hugo (web between the numb and in index finger af hand) not having the AV fistule. pain degree during arterovenous fistula puncture was measured whith using a subjective pain scale (visual analogue scale).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508317494N15**
Registration date: **2015-10-13, 1394/07/21**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-10-13, 1394/07/21

Registrant information

Name
Masoumeh Bagheri Nesami
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Mazandaran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effect of hugo point ice massage with 2% lidocaine gel on puncture- relted pain of fistula in hemodialysis patients.

Public title

The comparison of effect of hugo point ice massage with 2% lidocaine gel on puncture- relted pain of fistula in

hemodialysis patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: no pain whole body before insert of needle in to fistule exclusion criteria: age>18 no disease of preferal vascular and neuropathy: no known history of depression: capable oral and visual relation: oriented: starting hemodialysis for at least 3 months. Exclusion criteria: known allergies or sensitivities to lidocaine gel 2%: need to try for more of once: cognitive disorders: skin problems in the areaof massage: drug abuse 3 h before insert of needle in to fistule.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this randomized study, 37 patients with the software Rand between function Excel randomly were assigned to two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical

Street address

Ethics Committee of Mazandaran University of Medical,Vice chancellor for research, Moalem square, Sari, Mazandaran,Iran.

City

Sari

Postal code

4816715793

Approval date

2015-09-06, 1394/06/15

Ethics committee reference number

IR.MAZUMS.REC.94-1736

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.9

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Pain

Timepoint

before intervention and after every intervention

Method of measurement

Visual analoug scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: First patients hemodialys in the intervention group lidocaine gel complete pain visual analog scale and pain intensity evaluate and record by patients immediately after cannulation without any intervention on visual analogue scal During next session a hemodialys in group all patients receive lidocaine gel 2% 12 minute before AVF puncture in area of 5 cm2 amount 2 gr at the designated site no cover is placing at the designated site then gel remove and the skin disinfect before venopuncture and pain intensity of needle insertion evaluate and record by patients immediately after cannulation on visul analogue scale.

Category

Treatment - Drugs

2

Description

Intervention group 2: patients hemodialys in the intervention group hugo point ice mssege complete pain visual analog scale and pain intensity evaluate and record by patients immediately after cannulation without any intervention on visual analogue scal During next session hemodialys in group all patients the next session of hemodialys received ice massage on rotating at the 10 minute before arteriovenous fistula puncture (cold application 2*2*2 was done with ice cubes wrapped in gloves on the web between the thumb and index finger of the hand not having the AV fistula (hugo) massage during the injection lasts about 2 minutes, pain degree during arterio- venous fistula puncture was measured

with using a subjective pain scale (Visual analogue scale).

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemeh zahra hospital

Full name of responsible person
Dr Masoumeh Bagheri- Nesami

Street address
Mazandaran University of Medical Sciences, three-way joibar, highway bsij, Imam square, Sari, Mazandaran, Iran

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research Mazandaran University of Medical Sciences.

Full name of responsible person
Dr Ahmad Ali Enayeti

Street address
Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Square, Sari, Iran.

City
Sari

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 Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Dr masumeh Bagheri Nesami

Position
PHD/ faculty member

Other areas of specialty/work

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Person responsible for updating data

Contact

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