Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of effect lidocaine gel and inhalation of lavender aromatherapy on pain score of arteriovenous fistula puncture in hemodialysis patients

Protocol summary

Summary

Patients undergoing hemodialysis are exposed to stress and pain from approximately 300 punctures per year to their arteriovenous fistula. AVF punctures lead to a considerable degree of pain, due to the caliber and length of the bevel of fistula needles. Alleviation of this pain might improve their acceptance of the procedure and thus, their quality of life. The purpose of this study is comparison the effect of lidocaine gel and inhalation of lavender aromatherapy on pain intensity of arteriovenous fistula puncture in heamodialysis patients. This is a before and after clinical trial study. This study include 40 heamodialysis patients , first pain intensity of puncture measure without any intervention after needle insertion in arteriovenous fistula . one week later ,all patients receive lidocaine2% gel 15-20min before AVF puncture and 2week later , same patients inhale lavender aromatherapy 5min before AVF puncture. Pain intensity of needle insertion evaluate and record by patients immediately after cannulation on visual analogue scale. Interventions conduct in the three consecutive heamodialysis sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403082226N13**
Registration date: **2014-04-12, 1393/01/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-04-12, 1393/01/23

Registrant information

Name

Mansooreh Aliasgharpour

Name of organization / entity

Nursing & midwifery faculty, Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect lidocaine gel and inhalation of lavender aromatherapy on pain score of arteriovenous fistula puncture in hemodialysis patients

Public title

Comparison of effect lidocaine gel and inhalation of lavender aromatherapy on pain of arteriovenous fistula puncture in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 18 yr of age or older; be conscious; non smoking; lake of damaged; denuded, or broken skin at the designated site; lake of known allergies or sensitivities to lidocaine, prilocaine or other local anesthetic; no sensitivities to lavender aromatherapy; non used of alcohol and opioid substances; have a good sense of smell; minimum of reading and writing; no history of mental disorders. Exclusion criteria: afflict severe cold or non have a healthy sense of smell; concomitant use of an analgesic within the previous 24 h; or previous use of lidocaine/ prilocaine cream; extend the time interval over 1 hour of drug administration; patient's unwillingness to continue the study; the patient died.

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Tehran University of Medical Sciences

Street address
Tehran university medical sciences-tehran

City
Tehran

Postal code
1419733171

Approval date
2014-02-20, 1392/12/01

Ethics committee reference number
93-01-28-25468

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
berore intervention and after every intervention

Method of measurement
Visual analoug scale

Secondary outcomes

empty

Intervention groups

1

Description
2 week later (washout) , same patients receive aromatherapy intervention. three drops of aromatherapy blend containing Lavender essence 10% were poured on cotton in cast containers, and the patient is asking to inhale it for 5 minutes from a distance of 7- 10 cm from the nose; and pain severity of venepuncture measure and record using the VAS . this intervention also conduct in the three consecutive dialysis sessions.

Category
Other

2

Description
one week later ,all patients receive lidocaine2% gel 15-20min before AVF puncture in area of 5cm2 at the designated site. No cover is placing at the designated site then gel remove and the skin disinfect before venepuncture and pain intensity of needle insertion evaluate and record by patients immediately after cannulation on visual analogue scale . this intervention conduct in the three consecutive dialysis sessions.

Category
Treatment - Drugs

3

Description
First patients complete a demographic questionnaire and pain visual analog scale and based on inclusion criteria entere into the study and pain intensity evaluate and record by patients immediately after cannulation without any intervention on visual analogue scale

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam khomeyni hospital in Meianeh

Full name of responsible person
Reyhaneh Abbaszadeh

Street address
Nosrat east street -Faculty of nursing and midwifery - Tohid square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Akbar Fotoohi

Street address
4th Floor-The Center Building of Tehran University of Medical Sciences, Keshavarz Blvd, Ghods St.

City
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

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MSc student of critical care nursing

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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