

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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 hemodialysis patients. This is a before and after clinical trial study. This study include 40 hemodialysis patients , first pain intensity of puncture measure without any intervention after needle insertion in arteriovenous fistula . one week later ,all patients receive lidocaine 2% 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 hemodialysis 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

Mansoorreh Aliasgharpour

Name of organization / entity

Nursing & midwifery faculty, Tehran University of Medical Sciences

Country

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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

City

Tehran

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

Tehran

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

Full name of responsible person

Reyhaneh Abbaszadeh

Position

MSc student of critical care nursing

Other areas of specialty/work

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Full name of responsible person

Mansooreh Aliasgharpour

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Reyhaneh Abbaszadeh

Position

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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