Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Compare auditory distraction and visual distraction on pain, stress and vital sign changes from due to needles insertion into arteriovenous fistula in elderly patients undergoing hemodialysis

Protocol summary

Summary

The aim of this study is to compare two methods of visual distraction and auditory distraction to reduce the pain, stress and vital sign changes of the fistulas needles in hemodialysis elderly patients. For this purpose, a double blind controlled randomized clinical trial study is conducted on 120 hemodialysis elderly patients. The population of all hemodialysis elderly patients referred to the Ghiasi hospital. Through purposive sampling, patients were selected and randomly assigned to three groups will be (Routine method, visual distraction, and auditory distraction). Each sample group includes 40 patients. Each intervention will be done at three intermittent hemodialysis sessions. Demographic and clinical characteristics of the patients will be recorded with questionnaire. For the auditory distraction intervention group at three time nature based sounds and in visual distraction intervention group at three time films about nature will be done for 20 minutes. The intensity of stress before injection and the intensity pain after injection will be evaluated and recorded. Vital signs before and after the injection will be measured. All of the needles will be of the same material and size. Finally, the degree of pain, stress and vital sign changes resulted of the three groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709047529N14**
Registration date: **2017-09-19, 1396/06/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

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Name of organization / entity
Shahed University

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Recruitment status
Recruitment complete

Funding source
Shahed University Vice chancellor for research

Expected recruitment start date
2017-07-23, 1396/05/01

Expected recruitment end date
2017-11-22, 1396/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Compare auditory distraction and visual distraction on pain, stress and vital sign changes from due to needles insertion into arteriovenous fistula in elderly patients undergoing hemodialysis

Public title

The effect distraction on patients undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: the desire to participate in the study; over 60 years old; hemodialysis patients who have at least three session of dialysis at week; patients who have at least three months past of their fistula embedding; without alcohol and drugs consumption; the absence of cognitive impairment; not having vision or hearing problems; no history of mental illness with doctor approval. Exclusion criteria: patient dissatisfaction to continue participation in the study; lack of turn later; candidate for a transplant; using analgesic or non-pharmacological to reduce pain in the past 24 hours; in need of a second needle insertion into arteriovenous fistula in case of failure in the first of the fistulas needles; pain existence in the other parts of body.

Age

From **60 years** old to **139 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran.

City

Tehran

Postal code

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

Shahed.REC.1395.117

Health conditions studied

1

Description of health condition studied

Arteriovenous fistula puncture-related complication in hemodialysis patients

ICD-10 code

T82.4

ICD-10 code description

Mechanical complication of vascular dialysis catheter

Primary outcomes

1

Description

intensity of pain

Timepoint

After every intervention and immediately after the fistula needle

Method of measurement

Visual Pain Scale

2

Description

quality of pain

Timepoint

After every intervention and immediately after the fistula needle

Method of measurement

short-form McGill pain questionnaire

3

Description

Blood pressure

Timepoint

After every intervention and immediately after the fistula needle

Method of measurement

Checklist

4

Description

Respiratory rate

Timepoint

After every intervention and immediately after the fistula needle

Method of measurement

Checklist

5

Description

heart rate

Timepoint

After every intervention and immediately after the fistula needle

Method of measurement

Checklist

6

Description
stress
Timepoint
After every intervention and before the fistula needle
Method of measurement
Stress visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Interventions 1: For the auditory distraction intervention group at three intermittent hemodialysis sessions, nature based sounds at three time films about nature will be done for 20 minutes. Skin will be disinfected for vein puncture. Fistula is then punctured. In each intervention, the intensity of stress before injection and the intensity pain after injection will be evaluated and recorded.
Category
Other

2

Description
For the visual distraction intervention group at three intermittent hemodialysis sessions, films about nature will be done for 20 minutes. Skin will be disinfected for vein puncture. Fistula is then punctured. In each intervention, the intensity of stress before injection and the intensity pain after injection will be evaluated and recorded
Category
Other

3

Description
Skin will be disinfected for vein puncture. Fistula is then punctured. at three intermittent hemodialysis sessions, the intensity of stress before injection and the intensity pain after injection will be evaluated and recorded
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghiasi Hospital
Full name of responsible person
Mina Ghadimi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University Vice Chancellor For Research
Full name of responsible person
Dr. Zahra Kiasalari
Street address
Shahed University, Opposite to Holy Shrine Of Imam Khomeini, Tehran-Qom Express Way, Tehran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University Vice Chancellor For Research
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
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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