

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

2017-09-19, 1396/06/28

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

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

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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

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work