

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effecting of Arnica ointment and distraction on the pain caused by fistula needles in hemodialysis patients in Zahedan University of Medical Sciences Hospital's in 2017

Protocol summary

Study aim

Determine effecting of Arnica ointment and distraction on the pain caused by fistula needles in hemodialysis patients in Zahedan University of Medical Sciences Hospitals

Design

In this study, 93 hemodialysis patients referred to Ali Ibn Abitaleb and Khatam (peace be upon him) Hospital in Zahedan were selected based on inclusion criteria. The participants were randomly divided into two groups, including intervention and control group.

Settings and conduct

This study was conducted in dialysis unit at Ali Ibn Abitaleb and Khatem (peace be upon him) Hospital in Zahedan. Arnica cream in Arnica group, playing pictures along with music in distraction group and Vaseline cream will be used as placebo in control group before the cannulation. Uniform Arnica and Vaseline cream will be used for blinding. Also pain score will be measured and recorded by a research assistant without knowledge about the applied cream.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients aged over 18 years. 2- Consciousness, ability to communicate and collaborate. 3- Patients needed hemodialysis at least twice a week. 4- Taking no sedatives or any opiate drugs 6 hours before hemodialysis. 5- Absence of pain in other organs. 6- Absence of skin issues or Anesthesia at the vascular access point. 7- Diabetic patients without neuropathy. Exclusion criteria: 1- Developing an ulcer in fistula at any process of study 2- Displacement of fistula needles in appropriate place at first cannulation. 3- Patient death.

Intervention groups

Arnica cream group: Arnica cream will be applied to area about 5 cm² above the fistula 60 minutes before fistula needling and then the cannulation will be proceeded. Distraction group: The cannulation will be proceeded 10

minutes after playing pictures of nature. Control group: Vaseline cream will be applied to the area about 5 cm² above the fistula needle, then the cannulation will be proceeded.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170806035520N3**

Registration date: **2018-02-05, 1396/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-05, 1396/11/16**

Update count: **0**

Registration date

2018-02-05, 1396/11/16

Registrant information

Name

Alireza Salar

Name of organization / entity

Faculty of nursing and midwifery Zahedan

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2482

Email address

salar@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-02-09, 1396/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effecting of Arnica ointment and distraction on the pain caused by fistula needles in hemodialysis patients in Zahedan University of Medical Sciences Hospital's in 2017

Public title

"The effect of Distraction on the pain of the needle fistula""Effect of Arnica on Fistula Needle Pain"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Consciousness, ability to communicate and collaborate. Patients needed hemodialysis at least twice a week. Taking no sedatives or any opiate drugs 6 hours before hemodialysis. Absence of pain in other organs. Absence of skin issues at the vascular access point. Diabetic patients without neuropathy.

Exclusion criteria:

Developing an ulcer in fistula at any process of study Displacement of fistula needles in appropriate place at first cannulation. Patient death

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized

Blinding (investigator's opinion)

Double blinded

Blinding description

double blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee Zahedan university of medical sciences

Street address

Administrative Complex of Khalij Fars Blvd, University of Medical Sciences, Dr Hasabi Square, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2017-12-24, 1396/10/03

Ethics committee reference number

IR.ZAUMS.REC.1396.288

Health conditions studied**1****Description of health condition studied**

Fistula needle pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

After the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

First interventionIn:In this method Arnica ointment is rubbed into the injection site at 5 centimeters with holder dressing 60 minute before the injection and dressing is removed after the one hour, then area is cleaned and injection is performed.This intervention is performed in two consecutive hemodialysis sessions.

Category

Prevention

2

Description

Secound Intervention group: Nature pictures and music are played using laptop and headphone and after 10 minutes, the injection is done while playing pictures and music.This intervention is performed in two consecutive hemodialysis sessions.

Category

Prevention

3

Description

Control group: In this method Vaseline ointment is rubbed into the injection site at 5 centimeters with holder dressing 60 minute before the injection and dressing is removed after the one hour, then area is cleaned and injection is performed.This intervention is performed in two consecutive hemodialysis sessions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebn abitaleb(s) hospital

Full name of responsible person

Alireza salar

Street address

Behdasht blvd, Zahedan Faculty of Nursing and Midwifery, Zahedan, Sistan and Baluchestan, Islamic Republic Of Iran

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9816913396

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salar293@gmail.com

2

Recruitment center

Name of recruitment center

Khatam(s) hospital

Full name of responsible person

Alireza salar

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr noormuhammad bakhshani

Street address

Zahedan University of Medical Sciences, Khalije Fars Boulevard, Dr Hesabi Square, Zahedan, Sistan and Baluchestan, Islamic Republic Of Iran

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bakhshani@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Ali Raghobi

Position

master student of nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Alireza Salar

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Associate professor

Latest degree

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Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available