

# 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 cm<sup>2</sup> 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 cm<sup>2</sup> 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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816913396

##### Phone

+98 54 3344 2482

##### Email

salar293@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Khatam(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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816913396

##### Phone

+98 54 3344 2482

##### Email

salar293@gmail.com

## 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

##### City

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##### Province

Sistan-va-Balouchestan

##### Postal code

98167-43463

##### Phone

+98 54 3329 5796

##### Email

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

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Behdasht blvd - Zahedan Faculty of Nursing and  
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**Email**

raghibi\_58@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Alireza Salar

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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salar@zaums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Ali Raghibi

**Position**

master student of nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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

**City**

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**Postal code**

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**Phone**

+98 54 3344 2482

**Email**

raghibi\_58@yahoo.com

**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