Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Compare Zayla-Cream and ice compress on the level of stress, pain and cardiovascular response from due to needles insertion into arteriovenous fistula in hemodialysis.

Protocol summary

Summary

The aim of this study is to compare Zayla-Cream and ice compress on the level of stress, pain and cardiovascular response from due to needles insertion into arteriovenous fistula in hemodialysis patients. Design: randomized, placebo-controlled, single-center, phase II clinical trial. How to do: The study population included patients undergoing hemodialysis via arteriovenous fistula in Imam Hossein hospital, Shahroud. By using simple random sampling 50 hemodialysis patients allocate in three groups (Zayla cream, ice pack and placebo). The main inclusion criteria: patients age 18 year or older; be conscious; at least three months past their fistula embedded; the absence of skin damage in the desired position and lack of skin allergy to local anesthetics. The main exclusion criteria: use of analgesics in the past 24 hours; the patient's unwillingness to continue the study and the patient died. Interventions: At first step the intensity of stress, pain and cardiovascular changes induced by vein puncture will be measured after using the ice pack (placebo) on the site of injection. One week later (wash out), patients put under the intervention with Zayla cream, so that cream with an area of 5 cm^2 will be applied 10 minutes before inserting the needle on the fistula, after one week (wash out) they will received ice packs 10 minutes before the fistula needle placed in the area. The intensity of stress before injection and the intensity pain after injection will be evaluated and recorded by visual stress analogue scale and visual pain analogue Scale, respectively. Vital signs before and after the injection will be measured. Each intervention will be done at two intermittent Hemodialysis sessions. The main outcome variable: pain, stress, systolic blood pressure, diastolic blood pressure and pulse.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050427744N1**
Registration date: **2016-06-11, 1395/03/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-11, 1395/03/22

Registrant information

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Ziba Ghoreishi
Name of organization / entity
Shahroud university of medical sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research; Shahroud University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Compare Zayla-Cream and ice compress on the level of stress, pain and cardiovascular response from due to needles insertion into arteriovenous fistula in hemodialysis.

Public title
Compare Zayla-Cream and ice compress on the level of stress, pain and cardiovascular response from due to needles insertion into arteriovenous fistula in hemodialysis.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: age over 18 years; being vigilant to time, place and persons at the time collecting the information; Hemodialysis patients who have at least two session of dialysis at week; patients who have at least three months past of their fistula embedding; absence of damaged skin in the desired positions; no known allergy to local anesthetics; without alcohol and drugs consumption; the minimum level of literacy; no history of mental illness with doctor approval. Exclusion criteria: Analgesic use in the past 24 hours; the patient's unwillingness to continue the study; the patient died.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences

Street address
Central building of Shahroud university of medical sciences ,Hafte Tir Square, Shahroud

City
Shahroud

Postal code
3614773955

Approval date
2016-04-12, 1395/01/24

Ethics committee reference number
IR.shmu.rec.1395.19

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
Stress

Timepoint
After every intervention and before the fistula needle

Method of measurement
Stress visual analogue scale

2

Description
Pain

Timepoint
After every intervention and mmediately after the fistula needle

Method of measurement
Visual analoug scale

3

Description
Blood pressure

Timepoint
After every intervention and before and after the fistula needle

Method of measurement
Stigno monometer

4

Description
Pulse

Timepoint
After every intervention before and after the fistula

Method of measurement

Analog clock with seconds

Secondary outcomes

empty

Intervention groups

1

Description

Interventions 1: At first, the patients complete a demographic questionnaire, based on it, the qualified patients will be enrolled in the study. At First week, the intensity of stress before injection and the intensity of pain after injection with putting of placebo will be evaluated and recorded by visual stress analogue scale and visual pain analogue Scale, respectively. Also heart and cardiovascular changes in arterial venous fistula will be measured before and after injection.

Category

Placebo

2

Description

Interventions 2: After one week, the intervention with Zaylapy cream will be done in which, in all patients, 10 minutes before inserting the needle in fistula, cream with the area of 5 cm2 will be applied to the area. Do not put a cover over the area, then the cream will be cleared and skin will be disinfected for Vncopanccher. Then, the intensity of stress before injection and the intensity of pain after injection with putting of placebo will be evaluated and recorded by visual stress analogue scale and visual pain analogue Scale, respectively. This intervention will be done at two intermittent Hemodialysis sessions.

Category

Treatment - Drugs

3

Description

Interventions 3: In this group, 10 minutes before inserting the needle in fistula, ice will be placed around the fistula. Then the skin will be dried and disinfected and needle inserted in fistula. The intensity of stress and vital signs before injection and the intensity of pain and vital signs after injection will be evaluated and recorded.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahroud Imam Hussein Hospital

Full name of responsible person

Ziba Ghoreishi

Street address

Shahroud, Imam Hosein Hospital

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research; Shahroud University of Medical Sciences

Full name of responsible person

Dr Mohammadhasan Emamian

Street address

Central building of Shahroud university of medical sciences ,Hafte Tir Square, Shahroud .

City

Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research; Shahroud 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

Shahroud university of medical sciences

Full name of responsible person

Ziba Ghoreishi

Position

Graduate student of Critical Care Nurses

Other areas of specialty/work

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Person responsible for scientific inquiries

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Faculty member

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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