Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of Arnigol cream on pain associated with arteriovenous fistula puncture among patients receiving hemodialysis

Protocol summary

Summary

Goals of the study: Investigating the effect of ARNIGOL cream on pain intensity due to needles insertion in hemodialysis patients. Study design: Double - blind randomized clinical trial. The method of the study includes: Study population: The patients undergoing hemodialysis in the hospitals of Ali Ibn Abi Taleb at Rafsanjan city and Shafa at Kerman city.Inclusion criteria: Patients were included if they were receiving hemodialysis through arteriovenous fistula at least two times a week for three consecutive months, did not suffer from neuropathies or peripheral vascular problems, had no sign of inflammation at fistula site. Exclusion criteria are unsuccessful puncture at the first attempt and participants' voluntary withdrawal from the study. Sample size: 71 subjects. Study Intervention: In this study intervention and control groups will conduct on one patient. In this regard for every hemodialysis patient two needles are needed(Arterial needle and venous needle) that insert consecutively(all of the needles will be of the same material and size) ,One puncture site was randomly allocated to the experiment and the other one to the placebo.Before needle insertion, the experiment and the placebo sites were treated for ten minutes with respectively five milliliters of Arnigol cream and vitamin A and D ointment, respectively. After inserting needles, pain intensity will be measured by Visual Analogue Scale (VAS). The patients and pain rater will blind on cream type.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112615965N8**
Registration date: **2017-04-20, 1396/01/31**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-04-20, 1396/01/31

Registrant information

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Rafsanjan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Scienes

Expected recruitment start date

2016-11-26, 1395/09/06

Expected recruitment end date

2016-12-26, 1395/10/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Arnigol cream on pain associated with arteriovenous fistula puncture among patients receiving hemodialysis

Public title

The effect of Arnigol cream on pain intensity caused by needles in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients were included if they were receiving hemodialysis through arteriovenous fistula at least two times a week for three consecutive months, were fully conscious, aged eighteen or more, did not suffer from neuropathies or peripheral vascular problems, had no sign of inflammation at fistula site, received no topical analgesic at fistula site prior to the study intervention, and had no known allergy to Arnigol cream. Exclusion criteria: Unsuccessful puncture at the first attempt and participants' voluntary withdrawal from the study

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **71**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

One puncture site randomly simple(flip the coin) will allocate to the experiment and the other one to the placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan

City

Rafsanjan

Postal code

7717932777

Approval date

2016-01-09, 1394/10/19

Ethics committee reference number

IR.RUMS.REC.1394.166

Health conditions studied

1

Description of health condition studied

Chronic renal failure

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Pain

Timepoint

Immediately after entering needles

Method of measurement

Based on a numerical scale VAS

Secondary outcomes

empty

Intervention groups

1

Description

For every hemodialysis patient two needles are needed(Arterial needle and venous needle) that insert consecutively, One puncture site was randomly allocated to the experiment and the other one to the placebo.Before needle insertion, the experiment sites will treat for ten minutes with respectively five milliliters of Arnigol cream(the cream is produce of GOLDARU company and its 100 grams contain 5g ARNICA extract). After inserting needles, pain intensity will be measured.

Category

Treatment - Drugs

2

Description

And other needle as control site scrubbing by placebo (vitamin A and D ointment) as the same amount (0.5 cc) 10 minutes before insertion. After inserting needles, pain intensity will be measured.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Talib Hospital, Rafsanjan and Shafa, Kerman

Full name of responsible person

Dr.Majid Kazemi

Street address

Faculty of Nursing and midwifery, Rafsanjan

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Majid Kazemi

Street address

Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan

City

Rafsanjan

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Rafsanjan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Majid Kazemi

Position

Phd

Other areas of specialty/work

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Web page address

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