

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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

###### Name

Majid Kazemi

###### Name of organization / entity

Rafsanjan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3425 7663

###### Email address

dr.kazemi.n@rums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Rafsanjan University of Medical Sciences

##### 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**

**Street address**

Rafsanjan University of Medical Sciences, Imam Ali  
Boulevard, Rafsanjan

**City**

Rafsanjan

**Postal code**

7717932777

**Phone**

+98 34 3425 5900

**Fax**

+98 34 3425 8497

**Email**

dr.kazemi.n@rums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Somayeh Nejadbagheri Zadeh

**Position**

MSc

**Other areas of specialty/work**

**Street address**

Rafsanjan University of Medical Sciences, Imam Ali  
Boulevard, Rafsanjan

**City**

Rafsanjan

**Postal code**

7717932777

**Phone**

+98 34 3425 5900

**Fax**

+98 34 3425 8497

**Email**

s\_nbagheri59@yahoo.com

**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*