

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparative Study on the Effect of Aloe Vera and Nitroglycerin Powder on the incidence and severity of phlebitis caused by peritoneal catheter

#### Protocol summary

##### Study aim

Comparison of the effect of aloe vera and nitroglycerine ointment on the incidence and severity of phlebitis induced by peritoneal veins catheter in patients admitted to internal wards of Sanandaj Kowsar Hospital in 1397

##### Design

clinical trial

##### Settings and conduct

Kowsar Hospital Sanandaj

##### Participants/Inclusion and exclusion criteria

Entry Requirements: Hospitalization in the internal part for at least 48 hours, voluntary participation in the study, 20 to 70 years of age, having a healthy upper limb, requiring 48 hours of intravenous catheter, absence of phlebitis in the site before insertion of the angioquate, failure to receive injurious medications to the artery wall (Diazepam, midazolam, amiodarone, vitamin C, levofloxacin and ciprofloxacin), non-use of anticoagulants, the use of alcohol as an antiseptic prior to the administration of the catheter, as well as a history of vascular, systemic, diabetes, skin disease, diseases Acute and severe infections, severe anemia, glaucoma, hypotension (systolic pressure less than 100 mm) . Immune deficiency, no chemotherapy, no intravenous feeding. The type of catheter is angioquate and not attached to heparin lacquer. Conditions for not admitting to the study: discharge from the hospital two days after the start of the intervention, unwillingness to continue cooperation in the study, lack of proper and timely use of the Aloe vera and nitroglycerine ointment during the study, rupture or withdrawal of the angioconection before 48 hours , Getting sick for any reason and getting the intravenous line in the same.

##### Intervention groups

Group A of Aloe Vera Powder was manufactured by Arian Kimia Co., and in group B, nitroglycerin ointment was manufactured by Torika Company at a concentration of 2% in the upper part of the Angiocate area in the width of 2 × 4 cm and covered with sterile coating (angioutic

glue) Will be worn.

##### Main outcome variables

phlebitis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181204041845N1**

Registration date: **2019-07-15, 1398/04/24**

Registration timing: **retrospective**

Last update: **2019-07-15, 1398/04/24**

Update count: **0**

##### Registration date

2019-07-15, 1398/04/24

##### Registrant information

##### Name

samira mohammadian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3372 5645

##### Email address

mohammadian.s@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-20, 1396/12/29

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparative Study on the Effect of Aloe Vera and Nitroglycerin Powder on the incidence and severity of phlebitis caused by peritoneal catheter

**Public title**  
Comparative Study on the Effect of Aloe Vera and Nitroglycerin Powder on the incidence and severity of phlebitis caused by peritoneal catheter

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Hospitalization in the internal part for at least 48 hours, voluntary participation in the study, 20 to 70 years of age, having a healthy upper limb, requiring 48 hours of intravenous catheter, absence of phlebitis in the site before insertion of the angioquate, failure to receive injurious medications to the artery wall (Diazepam, midazolam, amiodarone, vitamin C, levofloxacin and ciprofloxacin), non-use of anticoagulants, the use of alcohol as an antiseptic prior to the administration of the catheter, as well as a history of vascular, systemic, diabetes, skin disease, diseases Acute and severe infections, severe anemia, glaucoma, hypotension (systolic pressure less than 100 mm) More mercury). Immune deficiency, no chemotherapy, no intravenous feeding. The type of catheter is angioquate and not attached to heparin lacquer.  
**Exclusion criteria:**  
Conditions for not admitting to the study: discharge from the hospital two days after the start of the intervention, unwillingness to continue cooperation in the study, lack of proper and timely use of the Aloe vera and nitroglycerine ointment during the study, rupture or withdrawal of the angioconection before 48 hours , Getting sick for any reason and getting the intravenous line in the same.

**Age**  
From **20 years** old to **70 years** old

**Gender**  
Both

**Phase**  
0

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **150**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
IPatients will be selected by simple sampling method and will be divided into three groups: A (nitroglycerin), B (Aloe Vera), and (C) by simple random allocation in the groups using the four-block software.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this one-sided study, only participants are unaware of the allocation of study groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
kurdistan university of medical science  
**Street address**  
Kurdistan University of Medical Sciences, lower than Ghods Hospital, Pasdaran Avenue  
**City**  
sanandaj  
**Province**  
Kurdistan  
**Postal code**  
6618634683

**Approval date**  
2018-12-25, 1397/10/04

**Ethics committee reference number**  
IR.MUK.REC.1397.261

**Health conditions studied**

**1**

**Description of health condition studied**  
phlebitis  
**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**

**1**

**Description**  
Phlebitis  
**Timepoint**  
هر 12 ساعت پس از مداخله به مدت 48 ساعت  
**Method of measurement**  
5-degree phlebitis observation scale

**Secondary outcomes**

**1**

**Description**  
Cutaneous complications  
**Timepoint**

Every 12 hours for 48 hours  
**Method of measurement**  
see

## Intervention groups

### 1

**Description**  
Intervention group:  
**Category**  
Prevention

### 2

**Description**  
Intervention group:  
**Category**  
Prevention

### 3

**Description**  
Control group:  
**Category**  
Placebo

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Kowsar Hospital  
**Full name of responsible person**  
Samira Mohammadian  
**Street address**  
Kurdistan University of Medical Sciences, lower than  
Ghods Hospital, Pasdaran Avenue  
**City**  
sanandaj  
**Province**  
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+98 87 3182 7272  
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+98 87 3366 4651  
**Email**  
samiraavin@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Sanandaj University of Medical Sciences  
**Full name of responsible person**  
Mohammad Fathi  
**Street address**

Kurdistan University of Medical Sciences, lower than  
Ghods Hospital, Pasdaran Avenue

**City**  
Sanandaj  
**Province**  
Kurdistan  
**Postal code**  
6618634683  
**Phone**  
+98 87 3362 7636  
**Email**  
fathi\_sanana@yahoo.com

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Sanandaj 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**  
Sanandaj University of Medical Sciences  
**Full name of responsible person**  
Mohammad Fathi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Kurdistan University of Medical Sciences, lower than  
Ghods Hospital, Pasdaran Avenue  
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fathi\_sanana@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Mohammad Fathi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Email**

samiraavin@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The whole potential data is unpublished after being unidentifiable

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Researchers working in academia and academia

**Under which criteria data/document could be used**

1

**From where data/document is obtainable**

1

**What processes are involved for a request to access data/document**

1

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Samira Mohammadian

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Kurdistan University of Medical Sciences, lower than Ghods Hospital, Pasdaran Avenue

**City**

Sanandaj