Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 angiocontection 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)

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+98 87 3372 5645

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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 angiocontection 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

lPatients 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

lIn 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 مدت48ساعت

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

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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

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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