Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of sesame oil and Chlorhexidine Gluconate solution 2% on the prevention of phlebitis related to peripheral venous catheter in patients admitted to the CCU wards

Protocol summary

Summary

This study will be conducted to determine the effect of external use of Sesame oil (SO) and Chlorhexidine Gluconate solution 2% in prevention of phlebitis related to peripheral venous catheter in patients admitted to the CCU wards of AJA hospitals Tehran. Materials & Methods: 60 patients who admitted in CCU, were enrolled in a clinical trial and they randomly divided in three equal, control & intervention 1 and 2, groups. in 1 intervention group(SO), as 5 drops of sesame oil, will be rubbed 5 cm around the area of intravenous catheter with a Clean Applicator and a new IV dressing will be fixed . for the other intervention group, Chlorhexidine Gluconate solution 2% will be sprayed at the same radius. from the first day, intervention will be done three times (every 24 hours during 72 hours). In the control group, every 24 hours, only the severity of phlebitis will be graded. Data tools included a bipartite questionnaire (demographic Q & clinical Q) and standard Visual infusion phlebitis Scale (VIP) for measurement of phlebitis (scored 0 to 5).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016053023446N7**
Registration date: **2016-07-30, 1395/05/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-30, 1395/05/09

Registrant information

Name

Fatemeh Teymouri

Name of organization / entity

AJA University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Aja University of Medical Science

Expected recruitment start date

2016-06-09, 1395/03/20

Expected recruitment end date

2016-09-10, 1395/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of sesame oil and Chlorhexidine Gluconate solution 2% on the prevention of phlebitis related to peripheral venous catheter in patients admitted to the CCU wards

Public title

Comparison of the effect of sesame oil and Chlorhexidine Gluconate solution 2% on the prevention of phlebitis .

Purpose

Prevention

Inclusion/Exclusion criteria

1. being 35-75 years of old 2.consciousness 3.Having informed consent 4.The first day of hospitalization, less than 24 hours have passed since the catheter 5. no

phlebitis at first 6.catheterization into arm vein 7.alcohol 70% as a disinfectant before use catheter for disinfectant 8.The patient has no previous phlebitis at the IV insertion site 9.the patient will require at least 72 hours to catheter venous having venous catheter 10. Lack of skin and vascular disease 11. the patient is not allergic to Sesame and its products 12.no fever, At baseline 13.Patients with not impaired immune systems 14.Lack of leukemia and history of Chemotherapy 15.No need for hemodialysis 16. lack of venous /arterial central line 17. Application No. 2o catheter 18.Lack of amiodarone therapy, vancomycin, phenytoin, diazepam, acyclovir, hypertonic products, calcium gluconate intravenous, cephalosporin Exclusion criteria:1.Refusing to continue the study 2.discharge before 72 hours 3.Injection drug or hypertonic solutions, Antibiotics and other drugs listed at Inclusion criteria ,Through via this catheter 4.Lost the catheter

Age
From **35 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Aja university of Medical Science

Street address
fatemi S, Etemad zade S, Aja university of Medical Science

City
Tehran

Postal code

Approval date
2016-05-09, 1395/02/20

Ethics committee reference number
IR.AJAUMS.REC.1395.05

Health conditions studied

1

Description of health condition studied
phlebitis

ICD-10 code
I80.9

ICD-10 code description
Phlebitis and thrombophlebitis of unspecified site

Primary outcomes

1

Description
phlebitis

Timepoint
daily

Method of measurement
Visual Infusion Phlebitis Scale

Secondary outcomes

1

Description
pain, redness, swelling

Timepoint
daily

Method of measurement
observation, interview

Intervention groups

1

Description
at first day, in 1 intervention group(SO), as 5 drops of sesame oil, will be rubbed 5 cm around the area of intravenous catheter with a Clean Applicator by reasercher and a new IV dressing will be fixed. This continues for 24 and 48 hours later by a research assistant.

Category
Prevention

2

Description
In the control group, every 24 hours (for 72 hours) only the severity of phlebitis will be graded and a new IV dressing will be fixed.

Category
Prevention

3

Description
for the other intervention group, Chlorhexidine Gluconate solution 2% will be sprayed at 5 cm around the catether and after drying, a new IV dressing will be fixed. This

continues for 24 and 48 hours later by a research assistant.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
besat hospital , ccu

Full name of responsible person

Street address
afsariye S

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Aga University of Medical Science

Full name of responsible person
Farsi Zahra

Street address
Shariati S, Kaj S, Aja Nursing Factuly

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Aga University of Medical Science

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
Aja university of Medical Science

Full name of responsible person
Farsi Zahra

Position
PhD/Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Master of science nursing student

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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