Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect Aesculus hippocastanum extract on the prevention of phlebitis induced by peripheral intravenous catheters

Protocol summary

Study aim
Determination of the effect of Aesculus hippocastanum extract on the prevention of phlebitis induced by peripheral intravenous catheters

Design
The clinical trial with control group, with parallel groups, double-blind, randomized, on 100 patients was divided into two intervention and control groups (50 people in each group) as a simple random allocation using block of four software.

Settings and conduct
Shariati Hospital, the study is double-blind (researcher-patient). both cream and placebo were packed in similar containers. After the placement of peripheral catheters in the test and control group, Indian chestnut and placebo are placed on the skin of insertion site. examination (0-24-48-72)

Participants/Inclusion and exclusion criteria
Inclusion criteria: hospitalization for at least 72 hours, age 18 and 60, iv-line implantation in a vein of the upper limb in a place without signs of phlebitis, 72-hour iv-line implantation - the patient being awake.Exclusion criteria: diabetes mellitus, skin disorders and types of eczema, systemic vascular diseases, severe anemia, immunodeficiency diseases, sensitivity to iv-line adhesive, undergoing chemotherapy, receiving anti-inflammatory drugs. Non-steroids oral, injection suppositories, suffering from acute chronic infectious diseases, receiving nitroglycerin, amiodarone and intravenous heparin, having fever and receiving antibiotic treatment to eliminate fever allergy to chestnut products

Intervention groups
After the placement of catheters (Angioket No. 20) in the test and control group, Indian chestnut extract (Venogol cream) and placebo cream will be placed on the skin of the angioket insertion site measuring 3x3 cm and covered with a sterile cover (angioket glue). Examination of the catheter insertion site in terms of the degree of phlebitis will be done at 0, 24, 48 and 72 hours using a visual phlebitis scale

Main outcome variables
Phlebitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220107053656N2**
Registration date: **2024-05-30, 1403/03/10**
Registration timing: **prospective**

Last update: **2024-05-30, 1403/03/10**
Update count: **0**

Registration date
2024-05-30, 1403/03/10

Registrant information

Name
kimya amouei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-30, 1403/05/09

Expected recruitment end date
2025-02-18, 1403/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect Aesculus hippocastanum extract on the prevention of phlebitis induced by peripheral intravenous catheters

Public title
The effect of Aesculus hippocastanum extract on the prevention of phlebitis induced by peripheral intravenous catheters
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalization in the wards of Shariati Hospital for at least 72 hours Age between 18 and 60 years IV-line implantation in a vein of the upper limb in a place without signs of phlebitis 72-hour IV-line implantation Patient being awake
Exclusion criteria:
Suffering from diabetes mellitus Suffering from skin disorders and types of eczema Suffering from systemic vascular disease Suffering from severe anemia Suffering from immunodeficiency diseases Allergic to iv-line adhesive Undergoing chemotherapy Receiving oral non-steroidal anti-inflammatory drugs, injections and suppositories Receiving intravenous amiodarone, and heparin and nitroglycerin Suffering from acute and chronic infectious diseases Having fever and receiving antibiotic treatment to eliminate fever Allergic to chestnut products
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done as available and 100 patients will be divided into two intervention and control groups (50 people in each group) by simple random allocation using block of four software
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a randomized and double-blind clinical trial (researchers and patients). In this way, the filling of the containers containing worms was done by someone other than the researcher or the sampler in the laboratory, and the containers of worms were named A and B for blinding, but blinding was not done for the statician.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in research of school of nursing midwifery rehabilitation
Street address
Nosrat, Tohid,
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2023-06-28, 1402/04/07
Ethics committee reference number
IR.TUMS.SHARIATI.REC.1402.053

Health conditions studied

1

Description of health condition studied
Phlebitis induced by peripheral intravenous catheters
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Phlebitis
Timepoint
Hours: 0,24,48 and 72
Method of measurement
Visual Infusion Phlebitis scale

Secondary outcomes

empty

Intervention groups

1

Description

After the placement of peripheral catheters (Angioket No. 20) in the test group, Indian chestnut extract (Worm Worm) on the skin of the angioket insertion site measuring 3x3 cm and in the placebo cream control group, on the skin of the angioket insertion site measuring 3x3 cm centimeter will be placed and it will be covered by a sterile cover (angioket glue). Daru Nama cream will be prepared by the pharmaceutical laboratory of Iranian School of Medical Sciences in Tehran. In order to blind patients and researchers to the intervention, both cream and placebo will be packed in similar containers and will be provided to the researcher. The occurrence of phlebitis and its degrees will be checked within 72 hours from the time of placing angioket and cream, at zero, 24 and 48 hours.The examination of the position in 24-hour intervals in terms of the occurrence and severity of phlebitis will be done by one of the researchers and one of the colleagues working in the relevant department to ensure reliability between the two evaluators. Based on the study design and ethical considerations, in both groups after examining the position using the visual scale of phlebitis in terms of its development and severity, the samples will be excluded from the study as soon as grade 2 or more phlebitis develops in them, and only samples They will remain in groups with phlebitis of 0 and 1

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati hospital
Full name of responsible person
Arpi Manookian
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Jalal al ahmad three ways, North Kargar street, Tehran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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6th floor of Research and Technology Vice-Chancellor, Central Organization of the University, corner of Quds St., Keshavarz Blvd.
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Arpi Manookian
Position
Associate professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available