Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation the effect of the 24 and 48-hour changing in chloride sodium 0.9% used in infusion of drug on the amount of phlebitis and serum infection

Protocol summary

Study aim

Determining the effect of 24 and 48 hours replacement of sodium chloride serum used in drug infusion on the rate of infection and phlebitis

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 300 patients. Permutation blocks were used for randomization.

Settings and conduct

Participants are selected from patients admitted to the internal medicine and surgery wards of Shirvan Hospital and are randomly assigned to the experimental and control groups. Due to the nature of the study, it is not possible to blind the participants. The researcher records the time and date of placement of the serum and catheter, and every 6 hours the site will be monitored for phlebitis. In the experimental and control groups, serum will be changed 48 and 24 hours, respectively. At the end of these times, some of the serum is sterilized and sent to a laboratory where it is cultured by a blind laboratory expert. After 48 hours, if more than fifteen colonies of microbial growth are seen in each sample, the result is positive culture and infectious serum. Blind statistics are analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People over the age of 18, patient consent or guardian, patient cooperation, having a drug to be infused, patients who are hospitalized for at least 48 hoursNo entry conditions: Pregnant, lactating, immunocompromised patients Suffering from skin and vascular diseases Patients receiving hypertonic substances and blood and its products, TPN solution Patients with sepsis and mental disorders Receiving anticoagulants If you have a local infection at the catheter injection site

Intervention groups

in the control group, the serum used in the infusion of drugs will be changed every 24 hours and in the intervention group every 48 hours.

Main outcome variables

Phlebitis, serum contamination

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20210307050610N1**
Registration date: **2021-05-11, 1400/02/21**
Registration timing: **prospective**

Last update: **2021-05-11, 1400/02/21**
Update count: **0**

Registration date

2021-05-11, 1400/02/21

Registrant information

Name

zahra Rezazade rezvani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3622 4562

Email address

rezazade96@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation the effect of the 24 and 48-hour changing in chloride sodium 0.9% used in infusion of drug on the amount of phlebitis and serum infection

Public title
Evaluation of serum replacement frequency used in drug infusion on serum contamination and incidence of phlebitis
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
People over the age of 18 patient consent or caregiver patient cooperation having a drug to be infused patients who have been hospitalized for at least 48 hours
Exclusion criteria:
Pregnant patients lactating patients immunocompromised patients Patients with skin and vascular diseases Patients receiving hypertonic serum and patients receiving blood and blood products patients receivingTotal parenteral nutrition Patients with sepsis patients with mental disorders Patients receiving anticoagulants If you have a local infection at the catheter injection site
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **300**
More than 1 sample in each individual
Number of samples in each individual: **2**
Samples of catheters and serum used in patients' infusions
Randomization (investigator's opinion)
Randomized
Randomization description
By simple random sampling method of people referring to Hashemi Rafsanjani Hospital in Shirvan who are eligible after sample selection is divided into two experimental groups (with 48-hour change of 0.9% sodium chloride serum) and the control group (with normal 24-hour change) be. In this study, individuals were assigned to two groups using permutation block method. In this method, A represents the individual receiving the intervention and B represents the individual in the control group. Considering the quadruple block; Instead of AABB code 0, give ABAB code 1, ABBA code 2, BAAB code 3, BBAA code 4 and BABA code 5. Then, using a table of random numbers, he randomly selected the starting point. Considering the order of the numbers in the table, we place the permutation corresponding to each number we encounter. So finally, by selecting the numbers from the table, how to assign a total of 300 people to the two groups will be determined
Blinding (investigator's opinion)
Double blinded
Blinding description
The data analyzer does not know which group the people are in. Laboratory samples are given to the laboratory expert anonymously based on numbers and he does not know if the samples are in the intervention or control group.
Placebo
Not used
Assignment
Parallel
Other design features
not

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences
Street address
Asadabadi
City
sabzvar
Province
Razavi Khorasan
Postal code
9617913112
Approval date
2021-03-06, 1399/12/16
Ethics committee reference number
IR.MEDSAB.REC.1399.185

Health conditions studied

1

Description of health condition studied
Phlebitis
ICD-10 code
T81.7
ICD-10 code description
Vascular complications following a procedure, not elsewhere classified

2

Description of health condition studied
Catheter-related infection
ICD-10 code
T85.7
ICD-10 code description
Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts

Primary outcomes

1

Description
Number of phlebitis according to Jackson criteria
Timepoint
During the period of hospitalization
Method of measurement
Jackson criteria

2

Description
Number of cases of serum contamination
Timepoint
24 hours in the control group and 48 hours in the experimental group
Method of measurement
Response of serum culture sample sent to laboratory

Secondary outcomes

1

Description
Number of catheter contamination cases
Timepoint
Discharge of the patient or 72 hours after catheter placement or catheter phlebitis
Method of measurement
Response of the catheter sample sent to the laboratory

Intervention groups

1

Description
Intervention group: The serum used in the infusion of drugs will be changed every 48 hours. At the end of 48 hours from the start of serum infusion, 5 cc of each serum was drawn with a syringe and sterile method and sent to the laboratory under sterile conditions and in the shortest possible time and each sample was cultured by a blind laboratory expert. Then count the number of colonies that appear and if more than fifteen microbial growths are seen in each container, the result of positive culture and the corresponding serum will be considered infected. If the number of colonies was less than or equal to 15 and the person was asymptomatic, serum is considered colonization.
Category
Treatment - Devices

2

Description
Control group: The serum control group used in the infusion of drugs will be changed every 24 hours. At the end of 48 hours from the start of serum infusion, 5 cc of each serum was drawn with a syringe and sterile method and sent to the laboratory under sterile conditions and in the shortest possible time and each sample was cultured by a blind laboratory expert. Then count the number of colonies that appear and if more than fifteen microbial growths are seen in each container, the result of positive culture and the corresponding serum will be considered infected. If the number of colonies was less than or equal to 15 and the person was asymptomatic, serum is considered colonization.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah hashemi rafsanjani hospital
Full name of responsible person
Hasan Khalili
Street address
No. 20, University Alley 19, University Street
City
Shirvan
Province
North Khorasan
Postal code
9461985697
Phone
+98 58 3622 4562
Email
Rezazade96@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Saghi Mohammad Hossain
Street address
Nuclear Martyrs Boulevard, Campus of the University of Medical Sciences, Management of the Center for the Study and Development of Medical Education
City
Sabzvar
Province
Razavi Khorasan
Postal code
9617913112

Phone
+98 51 4401 8455
Email
Saghi9@gmail.com
Grant name
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Hasan Khalili
Position
Professor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Campus of University of Medical Sciences,Nuclear Martyrs Blvd
City
Sabzvar
Province
Razavi Khorasan
Postal code
9617913112
Phone
+98 51 4408 6458
Email
khaalili894@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Hasan Khalili
Position
Professor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Vice Chancellor for Education, University, Tohid Shahr Blvd
City
sabzvar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4401 1300
Email
khalili894@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Zahra Rezazade rezvani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 20, University Alley 19, University Street
City
Shirvan
Province
North Khorasan
Postal code
9461985697
Phone
+98 58 3622 4562
Email
rezazade96@gmail.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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	Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary	