

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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 hours  
No 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 receiving Total 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

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Sabzevar University of Medical Sciences

##### **Full name of responsible person**

Saghi Mohammad Hossain

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Nuclear Martyrs Boulevard, Campus of the University of Medical Sciences, Management of the Center for the Study and Development of Medical Education

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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**  
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

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Nursery

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## Person responsible for updating data

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## 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  
**Data Dictionary**

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