

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

**A comparative study of two dressing techniques the sterile gauze dressing and the routine dressing method (leucoplast) in incidence and intensity of phlebitis associated with peripheral intravenous catheter site.**

### Protocol summary

#### Summary

The purpose of this research is the study of the comparison between sterile gauze dressing method and the routine dressing method (leucoplast) in incidence and intensity of phlebitis associated with peripheral intravenous catheter site. 80 bedridden patients in internal sections heart, CCU and PCCU in Imam Ali Cardiovascular center in Kermanshah put in two sampling groups of sterile gauze dressing or leucoplast based on blind randomizing. Place dressing in both groups is in the same way. After catheter placement, every 24 hours in a maximum of 72 hours period, the Status area phlebitis checked by using check list examination and observed by a researcher who does not know the patient groups. All of the samples of research trained in a same way for catheter care. Also there are reported a fixed instruction about dilution and constant infusion rate of intravenous drugs in patient's card and nurse report. After gathering information, it will be analyzed by 16th version of SPSS software and inferential statistics test cases

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201101085564N1**  
Registration date: **2011-04-10, 1390/01/21**  
Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2011-04-10, 1390/01/21

#### Registrant information

##### Name

fateme Hadadian Chaqayy

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1826 9394

##### Email address

fhadadian@kums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice - Chancellery of Research & Technology Affairs of Kermanshah University of Medical Sciences

#### Expected recruitment start date

2010-09-11, 1389/06/20

#### Expected recruitment end date

2011-01-20, 1389/10/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparative study of two dressing techniques the sterile gauze dressing and the routine dressing method (leucoplast) in incidence and intensity of phlebitis associated with peripheral intravenous catheter site.

#### Public title

A comparative study of two dressing techniques the sterile gauze dressing and the routine dressing method (leucoplast) in incidence and intensity of phlebitis

associated with peripheral intravenous catheter site.

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

Inclusion criteria: Having serum or IV medicine; Having no sensitivity to Leucoplast, Iodine or other medicines; Having no blood transfusion; having normal skin in the site that insert intravenous catheter; having no IV infusion of Hypertonic serum, having Systolic blood pressure upper 90 mm/Hg. Exclusion criteria: The patient discharging or expiring, before 72 hours insert intravenous catheter

#### **Age**

From **20 years** old to **90 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Kermanshah University of Medical Sciences, Vice -  
Chancellery of Research & Technology Affairs

###### **Street address**

Medical Science building No.2, In front of Imam Ali  
cardiovascular center, Shahid Beheshti Blvd.,  
Kermanshah, Iran

###### **City**

Kermanshah

###### **Postal code**

##### **Approval date**

2010-10-05, 1389/07/13

##### **Ethics committee reference number**

6966

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

phlebitis

##### **ICD-10 code**

Z45.2

##### **ICD-10 code description**

Adjustment and management of vascular access device

### **Primary outcomes**

#### **1**

##### **Description**

incidence of phlebitis

##### **Timepoint**

24,48,72 hourse after catheter placement

##### **Method of measurement**

phlebitis scale

#### **2**

##### **Description**

intensity of phlebitis

##### **Timepoint**

24,48,72 hourse after catheter placement

##### **Method of measurement**

phlebitis scale

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

In the intervention group after putting a new catheter, 5 × 5 cm sterile gauze is placed in the place of catheter and then will be fixed by leucoplast. If we made a mistake to put the catheter more than one time, we select a new location for injecting a new catheter. After catheter placement, for knowing the place of phlebitis symptoms, every 24 hours in a 72 hours period, the Status area is checked by a nurse who is unaware about patient group

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

In the control group after putting a new catheter the place will be fixed only by Leucoplast (Which typically used in Iran's/Kermanshah's hospitals now). In this group, like intervention group, if we made a mistake to put the catheter more than one time, we select a new location for injecting a new catheter. After catheter placement, for knowing the place of phlebitis symptoms, every 24 hours in a 72 hours period, the Status area is checked by a nurse who is unaware about patient group

##### **Category**

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Ali cardiovascular center in Kermanshah - Iran

##### Full name of responsible person

Kadivar Sakeine

##### Street address

Imam Ali cardiovascular center, Shahid Beheshti Blvd.  
Kermanshah

##### City

Kermanshah

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences, Vice -  
Chancellery of Research & Technology Affairs

##### Full name of responsible person

Doctor Farid Najafi

##### Street address

Kermanshah University of Medical Sciences, Vice -  
Chancellery of Research & Technology Affairs

##### City

Kermanshah

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Kermanshah University of Medical Sciences, Vice -  
Chancellery of Research & Technology Affairs

##### 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

F.Hadadian chaqayy

##### Position

MS in Medical Surgical Nursing / faculty mentor

##### Other areas of specialty/work

#### Street address

Nursing Midwifery school, Kermanshah University of  
Medical Sciences, kermanshah - Iran

#### City

Kermanshah

#### Postal code

#### Phone

+98 83 1828 2102

#### Fax

#### Email

fhadadian@kums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

F. Hadadian Chaqayy

##### Position

MS in Medical Surgical Nursing / faculty mentor

##### Other areas of specialty/work

##### Street address

Nursing Midwifery school, Kermanshah University of  
Medical Sciences, kermanshah - Iran

##### City

kermanshah

##### Postal code

##### Phone

+98 83 1828 2102

##### Fax

##### Email

fhadadian@kums.ac.r

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

##### Full name of responsible person

F. Hadadian Chaqayy

##### Position

##### Other areas of specialty/work

##### Street address

##### City

##### Postal code

##### Phone

##### Fax

##### Email

##### Web page address

## 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*