

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison of peripheral catheter complications during 72 and 96 hours after insertion

#### Protocol summary

##### Summary

The aim of this study is determination of the peripheral intravenous catheter complications during 72 and 96 hours after insertion, which is experimentally performed on patients after coronary artery bypass graft in heart surgery ward, in single blind way and using random block randomization sampling method. The inclusion criteria for the selection of samples: 1. Need to peripheral venous catheter for at least 72 hours. 2. Absence of any known Peripheral vascular disease 3. Receiving no immunosuppressive drugs. 4. Absence of bloodstream infection. 5. Lack of sensitivity to penicillin and receiving antibiotics according to routine protocol of heart surgery ward. The exclusion criteria include: 1. Changes in the type of intravenous medications during the study that cuts the sameness of drugs received by samples. 2. Accidental removal of catheter. 3. Removal of catheter when treatment is completed. 4. Skin allergy to adhesive dressing on catheter 5. Refusal to participate in research. The control group consist of 48 patients. Catheter replacement is done within 72 hours using routine method. There are 75 patients in intervention group. If the catheters of this group function properly to 72 hours, without any complications, will not be removed and the patient will be considered for 96 hours. After 96 hours, the catheter will be changed even if the catheter complications do not occur. In both groups, Catheters will be investigated in terms of complications including phlebitis, infiltration and occlusion.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015062419617N3**

Registration date: **2015-07-14, 1394/04/23**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-07-14, 1394/04/23

##### Registrant information

###### Name

Ezzat Paryad

###### Name of organization / entity

Guilan University of Medical Sciences, Shahid Beheshti Nursing and Midwifery Faculty

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3355 5056

###### Email address

e\_paryad@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Guilan University of Medical Sciences

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2016-02-20, 1394/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of peripheral catheter complications during 72 and 96 hours after insertion

##### Public title

Comparison of peripheral catheter complications during 72 and 96 hours after insertion

##### Purpose

Health service research

### **Inclusion/Exclusion criteria**

inclusion criteria: Need to peripheral venous catheter for at least 72 hours; Absence of any known Peripheral vascular disease (based on medical documents); Receiving no immunosuppressive drugs (based on medical documents); Absence of bloodstream infection (based on medical documents); Lack of sensitivity to penicillin and receiving antibiotics according to routine protocol of heart surgery ward exclusion criteria: Changes in the type of intravenous medications during the study that cuts the sameness of drugs received by samples; Accidental removal of catheter; Removal of catheter when treatment is completed; Skin allergy to adhesive dressing on catheter; Refusal to participate in research

### **Age**

No age limit

### **Gender**

Both

### **Phase**

N/A

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

*No information*

### **Sample size**

Target sample size: **123**

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

Randomized

### **Randomization description**

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

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

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

vice chancellor for research of Guilan university of medical science

##### **Street address**

Shahid Beheshti west boulevard, opposite of Sepah Bank, top of agency of Iran radiator, vice chancellor for Research Building

##### **City**

Rasht

##### **Postal code**

##### **Approval date**

2015-06-09, 1394/03/19

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

IR.GUMS.REC.1394.51

## **Health conditions studied**

### 1

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

complications of intravenous therapy

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

T80

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

Complications following infusion, transfusion and therapeutic injection

## **Primary outcomes**

### 1

#### **Description**

phlebitis at insertion site

#### **Timepoint**

in any shift until 72 and 96 hours

#### **Method of measurement**

the Infusion Nurses Society phlebitis scale

### 2

#### **Description**

infiltration

#### **Timepoint**

in any shift until 72 and 96 hours

#### **Method of measurement**

the Infusion Nurses Society infiltration scale

### 3

#### **Description**

occlusion of catheter

#### **Timepoint**

in any shift until 79 and 96 hours

#### **Method of measurement**

absence of serum flow even after aspiration

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

In control group, Catheter replacement is done within 72 hours using routine method without intervention.

#### **Category**

N/A

### 2

#### **Description**

in intervention group, If the catheters function properly to 72 hours, without any complications, will not be removed and the intervention in the form of keeping catheters to 96 hours will be performed.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Dr. Heshmat educational and medical center

**Full name of responsible person**

Ezzat Paryad

**Street address**

Shahid Beheshti highway, 15 Khordad avenue, Next to the Management and Planning Organization in Guilan Province

**City**

Rasht

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Guilan University of Medical Science

**Full name of responsible person**

Dr Abtin Heidarzade

**Street address**

Shahid Beheshti west boulevard, opposite of Sepah Bank, top of agency of Iran Radiator, vice chancellor for research building

**City**

Rasht

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Guilan 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**

Guilan University of Medical Science

**Full name of responsible person**

Ezzat Paryad

**Position**

nursing master of science/member of faculty

**Other areas of specialty/work****Street address**

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**Web page address**

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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*