

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of intermittent normal saline bolus during hemodialysis on adequacy of dialysis

Protocol summary

Summary

1) Objectives: The goal of the study is to investigate effect of intermittent normal saline bolus during hemodialysis on adequacy of dialysis. 2) Design: Our study design is a 4th phase of a randomized, cross over clinical trial. Fifty hemodialysis patients are chosen from Pan Azar Medical Educational Center, Gorgan, based on inclusion and exclusion criteria. They are allocated randomly into intervention and control group. 3) Setting and conduct: At the beginning of the study, we will measure the adequacy of dialysis at the first hemodialysis session. Then, the intervention is implemented on intervention group. After next two hemodialysis sessions, adequacy of dialysis is again measured. Blood clot in the venous chamber and dialyzer will be assessed and graded visually at the end of each hemodialysis session based on a grading table. Then one week is allowed for wash out period after which the groups are crossed over and all the steps will be repeated. 4) Participants: Participants are hemodialysis patients, at least 18 years old, and on maintenance hemodialysis for more than six months (4 hours, and three times per week), from Pan Azar Medical Educational Center, Gorgan. Their access types are Arteriovenous Fistula or Graft. 5) Intervention: Intervention is infusing 100 milliliters of normal saline, 3 times during hemodialysis in addition to following the standard protocol. The control group is dialyzed based on standard protocol. 6) Main outcome measures: The adequacy of dialysis is the primary outcome and the quality of clot formation in the venous chamber and dialyzer is the secondary outcome of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100324303N1**

Registration date: **2015-11-14, 1394/08/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-14, 1394/08/23

Registrant information

Name

Mitra Shirashiani

Name of organization / entity

Golestan University Of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 3253 4513

Email address

mitra.shirashiani@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Innovation of Golestan University of Medical Sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intermittent normal saline bolus during hemodialysis on adequacy of dialysis

Public title

Effect of intermittent normal saline bolus during hemodialysis on adequacy of dialysis

ir.goums.rec.1394.140

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with end-stage renal disease treated with maintenance hemodialysis for at least six months; Age above 18 years old; Willingness to participate in the study; On 3 times per week, 4-hours long maintenance hemodialysis; Arteriovenous Fistula or Graft access type; Receives 5000 units of unfractionated heparin during each session of hemodialysis; Hemoglobin concentration 9 to 14 grams per deciliter. Exclusion Criteria: Having acute debilitating disease (cardiovascular, hypertension, cancer and acute infection); Having systolic blood pressure below 90 and above 160 mm Hg.

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

50 patients will be allocated randomly (Block Randomization) in two groups (intervention and control).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Falsafi Educational Campus, Hirkan Boulevard

City

Gorgan

Postal code

4934174515

Approval date

2015-10-04, 1394/07/12

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z49

ICD-10 code description

Z49.1

Primary outcomes

1

Description

Adequacy of Hemodialysis (KT/V) and Urea Reduction Ratio (URR)

Timepoint

At first and third session of hemodialysis. After a one-week washout time, again at the first and third session of hemodialysis.

Method of measurement

Pre and post dialysis serum urea and calculation of URR and KT/V using formula recommended by Ministry of Health and Medical Education

Secondary outcomes

1

Description

Clot formation in extracorporeal tubing

Timepoint

At the end of each hemodialysis sessions

Method of measurement

By direct observation and grading

Intervention groups

1

Description

Intervention Group: One Hundred milliliters of normal saline is flushed through the arterial line of extracorporeal tubing three times during the 4-hour period of hemodialysis (once every hour) in addition to following the hemodialysis standard protocol; i.e., receiving 5000 units of unfractionated heparin during hemodialysis. The intervention is for 2 consecutive hemodialysis sessions.

Category

Treatment - Other

2

Description

Control Group: The group is dialyzed based on the standard protocol: Five thousands units of unfractionated

heparin are given during the 4-hour period of hemodialysis but no intermittent saline flush.

Category

Treatment - Other

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

Panj Azar Medical Educational Center

Full name of responsible person

Mitra Shirashiani

Street address

Panj Azar Street

City

Gorgan

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

Vice Chancellor for Research and Innovation,
Golestan University of Medical Sciences

Full name of responsible person

Masoud Khoshnia, MD

Street address

Falsafi Educational Campus, Hirkan Boulevard

City

Gorgan

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

Yes

Title of funding source

Vice Chancellor for Research and Innovation, Golestan
University of Medical Sciences

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**

Golestan University of Medical Sciences

Full name of responsible person

Einollah Mollaei

Position

Master of Nursing, Clinical instructor

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

School of Nursing and Midwifery, Falsafi Educational
Campus, Hirkan Boulevard

City

Gorgan

Postal code

4934174515

Phone

+98 17 3242 6900

Fax**Email**

mollaei@goums.ac.ir; einfa15@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Vice Chancellor for Research and Innovation,
Golestan University of Medical Sciences

Full name of responsible person

Homeira Khoddam, PhD

Position

PhD in Nursing

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

Falsafi Educational Campus, Hirkan Boulevard

City

Gorgan

Postal code

49341174515

Phone

+98 17 3242 1660

Fax**Email**

khoddam@goums.ac.ir;
homeira_khoddam@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Golestan University of Medical Sciences

Full name of responsible person

Mitra Shirashiani

Position

Student in Master of Science, Critical Care Nursing

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

Panj Azar Medical Educational Center, Panj Azar
Street

City

Gorgan

Postal code

4917761551

Phone

+98 17 3232 8630

Fax

+98 17 3236 8410

Email

mitra.shirashiani@goums.ac.ir;

mitra.shirashiani@yahoo.com;

shirashiani.mitra@gmail.com

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