

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The comparison of direction and distances of needles of hemodialys on arteriovenous fistula recirculation in hemodialysis patients

Protocol summary

Summary

This study will be conducted in order to comparison of direction and distances of needles of hemodialys on arteriovenous fistula recirculation in hemodialysis patients. There is no control group in this study, We will be selected 22 end stage renal disease patients with AV fistula that they were on haemodialysis more than 3 months. .The degree of recirculation will be measured with Urea based two needle technique method.recirculation will be measured with urea based two needle technique method recirculation Percent = $([P - A] \div [P - V]) \times 100$ During the four sessions of dialysis, direction and distance of needles for each patient will be change as follows: In first session, unidirectional needles with both directed to the heart and with a distance of 6 cm between them; In the second session, needles in opposite directions and with a distance of 6 cm between them; In the third session, unidirectional needles with both directed to the heart and with a distance of 3 cm between them; and in fourth session, needles in opposite directions and with a distance of 3 cm or more between them. The following protocol will be used for blood sampling.The ultrafiltration will be turned off approximately 30 minutes after the initiation of Haemodialysis and then arterial and venous line samples will be obtained. Access blood flow will be reduced to 50 mL/min and 15 to 30 seconds later, the Peripheral blood sample from the arterial blood line will be obtained.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082929581N1**

Registration date: **2016-11-29, 1395/09/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-29, 1395/09/09

Registrant information

Name

leila ghanbari afra

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3884 9038

Email address

lghanbari@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Qom University of Medical Sciences

Expected recruitment start date

2016-09-10, 1395/06/20

Expected recruitment end date

2017-01-09, 1395/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of direction and distances of needles of hemodialys on arteriovenous fistula recirculation in hemodialysis patients

Public title

The comparison of direction and distances of needles of hemodialys on recirculation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1-End stage renal disease patients under hemodialysis, with at least three times on a week for four hours per session 2-having arteriovenous fistula 3-initiation of hemodialysis for at least 6 months 4-Having good tolerance to dialysis and completing time of hemodialysis 5-Maintain blood flow rate for 350ml / min 6- Maintain dialysis fluid flow for 500ml / min 7- Use the same size dialyzers' membrane and same filter in all hemodialysis sessions 8-Use the one dialysis machine for one patient in all the hemodialysis sessions. Exclusion criteria: 1-cardiogenic shock during dialysis need to perform cardiopulmonary resuscitation 2-Unfinished dialyse sessions

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qom University of Medical Sciences

Street address

Research deputy of Qom university of Medical Sciences, No. 83, 4 lane, 1/1 Ave., Safashahr St., Qom.

City

Qom

Postal code

3713614975

Approval date

2014-06-07, 1393/03/17

Ethics committee reference number

IR.muq.Rec.1394.7

Health conditions studied

1

Description of health condition studied

end stage renal disease

ICD-10 code

N18.5

ICD-10 code description

مرحله انتهای بیماری کلیوی

Primary outcomes

1

Description

Decrease of recirculation Percent

Timepoint

Every other day

Method of measurement

The degree of recirculation will be measured with urea based two needle technique method recirculation Percent = $([P - A] \div [P - V]) \times 100$ P= Peripheral blood urea V= Intravenous blood urea A= The arterial blood urea.

Secondary outcomes

empty

Intervention groups

1

Description

In first session, unidirectional needles will be placed with both directed to the heart and with a distance of 6 cm between them.

Category

Treatment - Other

2

Description

In the second session, needles will be placed in opposite directions and with a distance of 6 cm between them.

Category

Treatment - Other

3

Description

In the third session, unidirectional needles will be placed with both directed to the heart and with a distance of 3 cm between them

Category

Treatment - Other

4

Description

in fourth session, needles will be placed in opposite

directions and with a distance of 3 cm or more between them.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

kamkar - Arabnia hospital

Full name of responsible person

Sideh Azam Vahedi

Street address

Dialyse ward, kamkar - Arabnia hospital, bajak street, Qom.

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Qom University of Medical Sciences

Full name of responsible person

Dr Hossein Saghaei

Street address

Research deputy of Qom university of Medical Sciences, No. 83, 4 lane, 1/1 Ave., Safashahr St., Qom.

City

Qom

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, Qom 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

Qom University of Medical Sciences

Full name of responsible person

Sideh Azam Vahedi

Position

Coach dialysis

Other areas of specialty/work

Street address

Dialyse ward, kamkar-Arabnia hospital, bajak street, Qom.

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Person responsible for updating data

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Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Sideh Azam Vahedi

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Other areas of specialty/work

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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