

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Stepwise profile of Fluid flow rate and increase Blood flow rate in Adequacy of Hemodialysis in Hemodialysis patients

Protocol summary

Study aim

Determine the Effect of Stepwise profile of Fluid flow and increase Blood flow on the Adequacy of Hemodialysis

Design

cross-over clinical trial which was conducted in two sequences ,Randomised, has control and intervention group.

Settings and conduct

This study included hemodialysis patients in Bu ali hemodialysis unit. So the total examination of patients, those that include the criteria for entry, isolated, 34 patients from randomly selected patients from the criteria of entry. After explaining the study method to patients, they are informed consent. These patients are examined in 2 phases. In the first phase, half of the patients receive 4 sessions in routine and the other half in 4 sessions by dialysis and blood flow profiling. In the second phase, two dialysis methods are transmitted between the two groups. The adequacy of hemodialysis is calculated and compared in two methods.

Participants/Inclusion and exclusion criteria

inclusion criteria: ESRD; three 4-hour sessions of dialysis per week; passing at least 3 months of treatment with hemodialysis; having a fistula; ability to participate in project; Age was above of 18 years. Exit criteria: active infection; referenced from other centers; heparin-free dialysis; Hospitalization for transplantation; Order Dialysis time less than 3:45

Intervention groups

The control group received 4 sessions of routine Hemodialysis for 3:45 hours. Patients in the intervention group, 4 sessions, are hemodialyzed by stepwise fluid flow profiling and increased blood flow.

Main outcome variables

the amount of Blood urea clearance and Hemodialysis Adequacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180407039218N1**

Registration date: **2018-06-12, 1397/03/22**

Registration timing: **retrospective**

Last update: **2018-06-12, 1397/03/22**

Update count: **0**

Registration date

2018-06-12, 1397/03/22

Registrant information

Name

Afsaneh Dashti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

a.dashti@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-26, 1397/03/05

Expected recruitment end date

2018-05-30, 1397/03/09

Actual recruitment start date

2018-05-31, 1397/03/10

Actual recruitment end date

2018-06-05, 1397/03/15

Trial completion date

empty

Scientific title

Effect of Stepwise profile of Fluid flow rate and increase Blood flow rate in Adequacy of Hemodialysis in Hemodialysis patients

Public title

Effect of Stepwise profile of Fluid flow rate and increase Blood flow rate in Adequacy of Hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Have a chronic renal failure and hemodialysis treatment
Age over 18 years. Are willing to participate in the research
Brachial arterial fistula
More than three months from the onset of hemodialysis
There are 3 dialysis sessions per week
Not having hepatitis, AIDS and septicemia
Not under chemotherapy
Do not have a history of bleeding
Acute heart failure

Exclusion criteria:

Dialysis order is less than 3:45
Patients with active infection
Patients referenced from other centers
Patients with heparin-free dialysis
Hospitalization for transplantation

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using random numbers table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences., Navab Ave., Bahonar Blvd

City

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Province

Qazvin

Postal code

3419759811

Approval date

2018-02-07, 1396/11/18

Ethics committee reference number

IR.QUMS.REC.1396.418

Health conditions studied

1

Description of health condition studied

Hemodialysis Adequacy

ICD-10 code

Z49.31

ICD-10 code description

Encounter for adequacy testing for hemodialysis

Primary outcomes

1

Description

Hemodialysis adequacy value

Timepoint

Calculate the adequacy of hemodialysis after each hemodialysis session

Method of measurement

Hemodialysis machine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, each patient hemodialyzed 4 sessions according to the stepwise fluid flow profile and increased blood flow. To implement this method, the patient is first connected to the B-braun (Dialog+) hemodialysis machine. After entering the patient's basic information such as height, weight, age, and gender, go to the dialysis fluid flow settings section, then select the step chart option. The maximum value is set to 800 cc / min and the minimum is 500 cc / min. Then, based on the patient's weight, if it was less than 65 kg, 15% or more than 65 kg, we would add 20% to the amount of base blood pump. Once again, go to the device configuration section and enable the Dialysis Compilation Calculation (KT / V) option by completing the patient's basic information. The patient's dialysis time should not be less than 3:45. At the end of the dialysis, we will write the numerical value of dialysis adequacy from the dialysis machine. The dialysis adequacy value is calculated after each dialysis session.

Category

Other

2**Description**

Control group: In this group, patients hemodialyzed 4 sessions with routine dialysis method. There are no changes or interventions in this group. At the end of each session, we will record the numerical value of dialysis adequacy (kt / v) calculated by the machine online.

Category

Other

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

Bu Ali Hospital

Full name of responsible person

Afsaneh Dashti

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Web page address<http://hosbooali.qums.ac.ir/Portal/home>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peymani

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Web page address<http://www.qums.ac.ir/Portal/Home/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Afsaneh Dashti

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

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Full name of responsible person

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Position

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

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

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