

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of distance of needle on the Dialysis Adequacy in hemodialysis patients in Razi Educational and Medical Hospital in Rasht.

Protocol summary

Study aim

The effect of direction and distance of needle on the Dialysis Adequacy in hemodialysis patients in Razi Educational and Medical Hospital in Rasht.

Design

A controlled clinical trial, with parallel groups, without blinding, randomized, on 60 patients undergoing hemodialysis. To randomize from Sealed Envelope Ltd. online randomization service 2019 was used.

Settings and conduct

This study will be performed on hemodialysis patients at Razi Hospital in Rasht in 2021. The Dagdras formula will also be used to measure dialysis adequacy. To measure BUN before and after dialysis, a blood sample will be taken from the arterial route immediately before the start of hemodialysis and at the last minute.

Participants/Inclusion and exclusion criteria

Hemodialysis patients with a minimum age of 18 years, patients with the end-stage renal disease with hemodialysis at least three times a week for four hours per session, a history of at least three months of dialysis, having a venous arterial fistula, completing the duration of dialysis in all sessions, Blood flow rate of at least 250 ml/min and dialysis flow rate of 500 ml/min will be entered. Exclusion criteria will include the need for cardiopulmonary resuscitation, incomplete dialysis sessions, and the patient's lack of cooperation for any reason.

Intervention groups

In this study, the control group will be the last dialysis session of each patient before the intervention. Eligible patients were randomly divided into two groups with random blocking, the experimental group with a distance of 3 cm and in the opposite direction, the experimental group with a distance of 6 cm and in the opposite direction.

Main outcome variables

Measurable outcome includes dialysis adequacy in hemodialysis patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201009048977N1**

Registration date: **2020-10-17, 1399/07/26**

Registration timing: **prospective**

Last update: **2020-10-17, 1399/07/26**

Update count: **0**

Registration date

2020-10-17, 1399/07/26

Registrant information

Name

Samad Karkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4723 2208

Email address

sami.karkhah@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-05, 1399/08/15

Expected recruitment end date

2021-02-03, 1399/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of distance of needle on the Dialysis Adequacy in hemodialysis patients in Razi Educational and Medical Hospital in Rasht.

Public title

The effect of distance of needle on the Dialysis Adequacy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing hemodialysis whose chronological age was above 18 solar years Patients with end-stage renal disease who underwent hemodialysis at least three times a week for four hours per session History of at least three months of dialysis Having a venous arterial fistula Complete the duration of dialysis in all sessions The blood flow rate of at least 250 ml per minute The dialysis flow rate of 500 ml per minute

Exclusion criteria:

Need for cardiopulmonary resuscitation Incomplete dialysis sessions Patient non-cooperation for any reason

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **3**

The adequacy of dialysis will be measured in three consecutive sessions by changing the direction and distance of arteriovenous needles by Kt/V based method.

Randomization (investigator's opinion)

Randomized

Randomization description

The initial sampling method is convenience sampling and the main sampling of the present study will be block randomization. Patients who met the inclusion criteria were randomly divided into two groups of block randomization with the size of 4 and 6 blocks, the experimental group with a distance of 3 cm and in the opposite direction, the experimental group with a distance of 6 cm and in the opposite direction. To generate a randomization list from the online randomization service Sealed Envelope Ltd 2019 was used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Shahid Beheshti St.

City

Rasht

Province

Guilan

Postal code

39841-41469

Approval date

2020-10-07, 1399/07/16

Ethics committee reference number

IR.GUMS.REC.1399.321

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

Z49

ICD-10 code description

Encounter for care involving renal dialysis

Primary outcomes

1

Description

Dialysis adequacy

Timepoint

Immediately before the start of hemodialysis and in the last minutes of hemodialysis

Method of measurement

Blood BUN measurement and calculation based on the Daugirdas-II formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: With a distance of 3 cm and in the opposite direction

Category

Treatment - Other

2

Description

Intervention group: With a distance of 6 cm and in the opposite direction

Category
Treatment - Other

3

Description

Control group: The last dialysis session of each patient before the intervention

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital, Rasht

Full name of responsible person
Samad Karkhah

Street address
Sardar Jangal Street

City
Rasht

Province
Guilan

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41448

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+98 13 3354 1001

Email
sami.karkhah@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Mohammad Taqi Moghaddam Nia

Street address
Shahid Beheshti St.

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moghaddamnia92@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source

Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Mohammad Taqi Moghaddam Nia

Position
Assistant Professor of Guilan University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Health in Emergency and Disaster

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Person responsible for scientific inquiries

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Position
Assistant Professor of Guilan University of Medical Sciences

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Samad Karkhah

Position

Master Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is 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

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers in the field of hemodialysis on request

From where data/document is obtainable

Communicate with the authors of the present study via email

What processes are involved for a request to access data/document

Communicate with the authors of the present study via email

Comments