

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

The effect of ultra filtration adjustment based on dry weight calculation by measuring serum sodium pre- dialysis on some of hemodialysis complications

Protocol summary

Summary

The aim of this clinical trial study is to determine the effect of ultrafiltration adjustment based on the dry weight calculation by measuring serum sodium pre-dialysis on some complications during hemodialysis. Population and sample: The study population will be patients undergoing hemodialysis who refer to 5th Azar hospital at the time of the study. 50 samples will be selected through convenience sampling. Then 25 patients will be allocated in intervention and control group randomly. Inclusion criteria include of a history of dialysis for at least one year; lack of diseases that cause fluid imbalance and exclusion criteria include disruption of blood flow through the fistula during the study. In the intervention group, the dry weight will be calculated using blood sodium before dialysis and then ultrafiltration set based on dry weight. In control group dry weight will be calculated in routine way and then hemodialysis complications will be measured in both groups. At the end of study two groups will be compared in terms of complications during hemodialysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042318649N2**

Registration date: **2015-09-09, 1394/06/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-09, 1394/06/18

Registrant information

Name

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Name of organization / entity

Golestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Sciences, Deputy of Research and Technology

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ultra filtration adjustment based on dry weight calculation by measuring serum sodium pre-dialysis on some of hemodialysis complications

Public title

The impact of dry weight calculation by measuring serum sodium pre- dialysis on some of hemodialysis complications

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: history of dialysis more than one year;

Age of 18-65 years; be able to communicate verbally; lack of syndrome of inappropriate antidiuretic hormone secretion and diabetes insipidus; lack of human immunodeficiency virus infection; lack of mechanical ventilation; do not have heart and liver failure; lack of an overactive adrenal gland; do not use serotonin inhibitor drugs; do not use anti-spasmodic and anti-hypertensive drugs four hours before of dialysis. Exclusion criteria: The patient's unwillingness to continue for cooperating during the study; disruption of blood flow through the fistula.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Golestan University of Medical Sciences

Street address

Falsafi Educational Campus, Shastkola Road

City

Gorgan

Postal code

Approval date

2015-05-22, 1394/03/01

Ethics committee reference number

IR.goums.rec.1394.8

Health conditions studied

1

Description of health condition studied

Renal failure

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Blood pressure disorders

Timepoint

At one hours interval during dialysis

Method of measurement

Blood pressure is measured using a sphygmomanometer

2

Description

Muscle cramps

Timepoint

At one hours interval during dialysis

Method of measurement

Using check list

3

Description

Nausea and vomiting

Timepoint

At one hours interval during dialysis

Method of measurement

Using check list

4

Description

Fatigue

Timepoint

At the end of dialysis

Method of measurement

Using Visual scale

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group: The blood sodium levels will be measured pre - dialysis to calculate patients' dry weight and then ultrafiltration will be set based on dry weight and dialysis will be done for 12 weeks.

Category

Treatment - Other

2

Description

In the control group: Dry weight will be determined in routine way and accordingly the ultrafiltration rate will be

adjusted and patient will be dialysis for 12 weeks.

Category

Treatment - Other

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

5 Azar medical and educational center

Full name of responsible person

Sara Saadatmand

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5 Azar Street

City

Gorgan

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

Golestan University of Medical Sciences, Deputy of research and technology

Full name of responsible person

Masoud Khosh Nia

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

Yes

Title of funding source

Golestan University of Medical Sciences, Deputy of research and technology

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**

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Position**Other areas of specialty/work****Street address****City****Postal code****Phone**

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Fax**Email****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