

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of bicarbonate high-dialysis on Body Mass Index, ABG, Albumin, Inflammation Indexes and Blood nutritional indexes in dialysis patients

Protocol summary

Study aim

The use of bicarbonate high-dialysis to improve the physical and biochemical indexes of nutritional status in dialysis patients

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

The study will be carried out in the hemodialysis department of the Persian Gulf Hospital in Bushehr. To avoid orientation in the study, we attempt to double-blind blindness. The first group is either participants or patients, and the second group is statistical advisers who will analyze the data. Therefore, patients will not be aware of the fact that they are in the case or control group. Also, the information in the case and control groups is named as Groups A and B and given to statistical consultants.

Participants/Inclusion and exclusion criteria

Entry Criteria: They have been under hemodialysis for at least 3 months Patients who are able to stand on the body composition Non-Entry Criteria: base HCO₃ in ABG above 24 kt/v<1/2 , Ca < 5/7 , K < 5/3

Intervention groups

Intervention group: use of dialysis fluid with bicarbonate 36 Control group: use of dialysis fluid with bicarbonate 32 (Standard and Common)

Main outcome variables

Body Mass Index, Albumin, Calcium, Phosphorus, Sodium, Potassium, HsCRP, TNF, PTH

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190130042563N1**

Registration date: **2019-06-30, 1398/04/09**

Registration timing: **retrospective**

Last update: **2019-06-30, 1398/04/09**

Update count: **0**

Registration date

2019-06-30, 1398/04/09

Registrant information

Name

Farnaz Hefzollah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3354 3581

Email address

dr.ammarbasri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of bicarbonate high-dialysis on Body Mass Index, ABG, Albumin, Inflammation Indexes and Blood nutritional indexes in dialysis patients

Public title

Effect of bicarbonate high-dialysis on Body Mass Index, ABG, Albumin, Inflammation Indexes and Blood nutritional indexes in dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

They have been under hemodialysis for at least 3 months
Patients who are able to stand on the body composition

Exclusion criteria:

base HCO₃ in ABG above 24 kt/v<1/2 , Ca < 5/7 , K < 5/3

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize, table of numbers will be used, with the pair numbers are control group and the individual numbers are the case group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Will not be told to patients that they are in the case or control group. Also, the data of the case and control groups are named as Groups A and B and given to statistical advisers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bushehr University of Medical Sciences

Street address

Bushehr university of Medical Science, Rishehr Ave.,
Salmane Farsi Blvd., Bahmani Town

City

Bushehr

Province

Boushehr

Postal code

7518759577

Approval date

2018-11-19, 1397/08/28

Ethics committee reference number

IR.DCUMS.REC.1397.115

Health conditions studied

1

Description of health condition studied

end-stage renal disease (ESRD)

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

High Sensitive C reactive Protein

Timepoint

Before the intervention and the end of the study (after 6 months)

Method of measurement

HS-CRP monobind kit

2

Description

TNF-a

Timepoint

Before the intervention and the end of the study (after 6 months)

Method of measurement

TNF-a kit

Secondary outcomes

1

Description

Body Mass Index

Timepoint

Before the intervention and the end of the study (after 6 months)

Method of measurement

Body Composition

2

Description

Albumin

Timepoint

Before the intervention and the end of the study (after 6 months)

Method of measurement

Albumin kit

3

Description

Blood level of phosphorus

Timepoint

Before the intervention and the end of the study (after 6 months)

Method of measurement

Phosphorus Measuring Kit

4**Description**

Blood level of Calcium

Timepoint

Before the intervention and the end of the study (after 6 months)

Method of measurement

Calcium Measuring Kit

5**Description**

Blood level of sodium

Timepoint

Before the intervention and the end of the study (after 6 months)

Method of measurement

Sodium Measuring Kit

6**Description**

Blood level of Potassium

Timepoint

Before the intervention and the end of the study (after 6 months)

Method of measurement

Potassium Measuring Kit

Intervention groups**1****Description**

Intervention group: Hemodialysis with high bicarbonate (36)

Category

Treatment - Other

2**Description**

Control group: Hemodialysis with common bicarbonate

Category

Placebo

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

Shohadaye Khaliye Fars Hospital

Full name of responsible person

Mehdi Mahmoudpour

Street address

Taleghani Blvd., Azadi square

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Bushehr

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Boushehr

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7517933755

Phone

+98 77 3345 5375

Email

mpgh@bpums.ac.ir

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

Boushehr University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology- Dr Gholamreza Khamisipour

Street address

Rishehr ave., Salmane Farsi Blvd., Bahmani Town

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bpums@bpums.ac.ir

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

Yes

Title of funding source

Boushehr 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**

Boushehr University of Medical Sciences

Full name of responsible person

Farnaz Hefzollah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Shohadaye Khalij Fars Hospital, Taleghani Boulevard,
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hefzollahf@yahoo.co.uk

Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Mehdi Mahmoudpour

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Farnaz Hefzollah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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