# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 و 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 و 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 Khalije Fars Hospital
**Full name of responsible person**
Mehdi Mahmoudpour
**Street address**
Taleghani Blvd., Azadi square
**City**
Bushehr
**Province**
Boushehr
**Postal code**
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
**City**
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**Province**
Boushehr
**Postal code**
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**Phone**
+98 77 3345 0236
**Email**
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

**Street address**

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## Person responsible for scientific inquiries

**Contact**

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Boushehr University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

Farnaz Hefzollah

**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

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**Postal code**

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**Phone**

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**Email**

hefzollahf@yahoo.co.uk

## 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