Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Sodium Bicarbonate supplementation on improving nutritional status amongst patients on Maintenance Hemodialysis.

Protocol summary

Study aim
The study aims to see the effect of sodium bicarbonate supplementation on the nutritional status of patients on maintenance hemodialysis

Design
Single-centre, randomized clinical trial

Settings and conduct
This single-center clinical trial will be conducted at the Pak Emirates Military Hospital (Dialysis Unit). Patients will be randomized to either a control or study group after consent. Hand grip strength, and triceps skinfold thickness along with serum bicarbonate, albumin, creatinine, and hemoglobin will be noted at baseline, 2, 4, 6 and 12 weeks..

Participants/Inclusion and exclusion criteria
Individuals from either gender who were > 18 years of age on twice weekly maintenance hemodialysis for more than 6 months, able to comply with study instructions, and having serum bicarbonate levels ≤23mmol/L were included in the study. Individuals having an active infection, unstable heart disease, congestive heart failure, limb amputation and renal tubular acidosis were excluded from the study. Moreover, patients on bisphosphonate therapy, and calcium or sodium bicarbonate therapy were also excluded.

Intervention groups
The participants were divided into 2 groups. The control group was not given any medication while the Study group was given tablet Sodium Bicarbonate 600mg three times a day orally.

Main outcome variables
Changes in hand grip strength, triceps skinfold thickness, serum bicarbonate, serum albumin, and hemoglobin will be noted.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240208060941N2**
Registration date: **2024-02-21, 1402/12/02**
Registration timing: **retrospective**

Last update: **2024-02-21, 1402/12/02**
Update count: **0**

Registration date
2024-02-21, 1402/12/02

Registrant information
Name
Muhammad Iqbal
Name of organization / entity
Pak Emirates Military Hospital/ National University of Medical Sciences
Country
Pakistan
Phone
+92 342 7007463
Email address
iqbalkharal2934@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-15, 1402/05/24

Expected recruitment end date
2023-08-30, 1402/06/08

Actual recruitment start date
2023-08-15, 1402/05/24

Actual recruitment end date
2023-08-26, 1402/06/04

Trial completion date
2024-03-15, 1402/12/25

Scientific title
Effect of Sodium Bicarbonate supplementation on improving nutritional status amongst patients on

Maintenance Hemodialysis.

Public title
Effect of Sodium Bicarbonate in improving health of Chronic Kidney Disease patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients from either gender: male or female Patients having > 18 years of age Patients on twice weekly maintenance hemodialysis for more than 6 months Patients able to comply with study instructions Patients having serum bicarbonate levels ≤23mmol/L
Exclusion criteria:
Patients having active infection or sepsis Patients with systemic conditions (unstable heart disease, congestive heart failure, dementia, cerebrovascular disease, hepatic impairment and renal tubular acidosis) Pateints with poor blood pressure Patients who had limb amputation in the past Patients on bisphosphonate therapy Patients being treated calcium or sodium bicarbonate therapy Patients not consenting to participate in the study
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: **26**
Actual sample size reached: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done using computer-generated sequences, prepared online.
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
Ethical Committee Pak Emirates Military Hospital Rawalpindi
Street address
Pak Emirates Military Hospital, Mall Road
City
Rawalpindi
Postal code
46000
Approval date
2023-08-08, 1402/05/17
Ethics committee reference number
A/28/ERC/624/23

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Nutritional Status
Timepoint
Before intervention and 2, 4, 6, 12, and 18 weeks post intitation of treatment
Method of measurement
Hand Grip Strength, Triceps Skinfold Thickness, Serum Albumin

Secondary outcomes

empty

Intervention groups

1

Description
Control group: This group will recieve no drug
Category
Treatment - Drugs

2

Description
Intervention group: This group will recieve sodium bicarbonate
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pak Emirates Military Hospital Rawalpindi
Full name of responsible person

Muhammad Iqbal
Street address
Pak Emirates Military Hospital, Abid Majeed Road
City
Rawalpindi
Postal code
46000
Phone
+92 342 7007463
Email
Iqbalkharal2934@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pak Emirates Military Hospital
Full name of responsible person
Muhammad Iqbal
Street address
Abid Majeed Road
City
Rawalpindi
Postal code
46000
Phone
+92 342 7007463
Email
Iqbalkharal2934@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pak Emirates Military Hospital
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
Pak Emirates Military Hospital
Full name of responsible person
Muhammad Iqbal
Position
Registrar Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Abid Majeed Road
City
Rawalpindi
Province
Punjab
Postal code
46000
Phone
+92 334 7131037
Fax
Email
Iqbalkharal2934@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Pak Emirates Military Hospital
Full name of responsible person
Muhammad Iqbal
Position
Registrar Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Abid Majeed Road
City
Rawalpindi
Province
Punjab
Postal code
46000
Phone
+92 334 7131037
Fax
Email
Iqbalkharal2934@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Pak Emirates Military Hospital
Full name of responsible person
Muhammad Iqbal
Position
Registrar Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Abid Majeed Road
City
Rawalpindi
Province
Punjab

Postal code
46000
Phone
+92 334 7131037
Fax
Email
Iqbalkharal2934@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The Deidentified Individual Participant Data Set, Study Protocol, Statistical Analysis Plan, and Informed Consent forms will be made available to desirous researchers upon reasonable requests, and after clearance from the institutional data registry body. The said documents will be shared in a non-editable format via email after scrutinizing the need for subject documents by the requesting authorities.
When the data will become available and for how long
The above-mentioned documents will be available after December 2024 for 5 years as per institutional data registry protocols.
To whom data/document is available
The data will be available only for non-commercial research purposes and will be provided to academic institutions only.
Under which criteria data/document could be used
The data/ document can be used for literary and non-commercial purposes.
From where data/document is obtainable
The Data can be obtained via email from: Dr Muhammad Iqbal Department of Medicine, Pak Emirates Military Hospital, Abid Majeed Road, Rawalpindi, Punjab, Pakistan, 46000. Email: iqbalkharal2934@gmail.com
What processes are involved for a request to access data/document
Data requests can be directly made to Dr Muhammad Iqbal via email provided earlier. After the request is received, it will submitted to the Institutional Data Control and Registry Committee for necessary verification and clearance of the requested documents. Any additional information required by the committee will be forwarded to the requestee via email. After satisfying the requirements of the Institutional Data Control and Registry Committee, the requested data/ documents will shared with the requesting person via suitable means. This process may take up to 6 weeks from the date of reception of the request.
Comments