

Correction of acidosis in hemodialysis patients. Effects on protein metabolism, investigated by tracer technique and messenger-ribonucleic acid determination for ubiquitin and proteasome subunits.

Submission date

29/03/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

03/07/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

26/07/2007

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Study objectives

Metabolic acidosis stimulates muscle protein breakdown, correction of acidosis results in decreased protein breakdown.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Ethics Committee of Karolinska Institute at Huddinge University Hospital on 11/01/1993, reference number: 196/96

Study design

Randomised, controlled, crossover design

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

End-stage renal failure

Interventions

Adjustments of acid-base balance - in each patient, protein turnover will be measured twice, at a standard bicarbonate concentration of <19 mmol/l and >25 mmol/l respectively, with an interval between the two measurements (random order) of 3-4 weeks. The acid-base status will be altered by adjusting the dose of bicarbonate (oral and/or via dialysis) and protein turnover will be measured when the predialysis bicarbonate level have been low or normal for at least one week.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Muscle protein turnover

Key secondary outcome(s)

1. messenger-Ribonucleic Acid (mRNA) for ubiquitin and proteasome subunits
2. Plasma and muscle intracellular amino acid concentrations
3. Serum albumin

Completion date

31/12/1998

Eligibility

Key inclusion criteria

1. Clinically stable hemodialysis patients
2. >18 Years of age

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Clinically obvious malnutrition
2. Ongoing infection
3. Diabetes mellitus
4. Untreated congestive heart failure
5. Treatment with corticosteroids or other immunosuppressive agents

Date of first enrolment

01/04/1997

Date of final enrolment

31/12/1998

Locations

Countries of recruitment

Sweden

Study participating centre

Karolinska University Hospital

Stockholm

Sweden

SE-171 76

Sponsor information

Organisation

Karolinska University Hospital (Sweden)

ROR

<https://ror.org/00m8d6786>

Funder(s)

Funder type

Government

Funder Name

Swedish Medical Research Council (ref: 11243 and 04210)

Funder Name

Gambro AB

Funder Name

Baxter Inc.

Funder Name

U.S. National Institutes of Health (R01 DK37175)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	01/09/2006		Yes	No

