ISRCTN27844532 https://doi.org/10.1186/ISRCTN27844532

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

Submission date	Recruitment status
29/03/2006	No longer recruiting
Registration date	**Overall study status**
03/07/2006	Completed
Last Edited	**Condition category**
26/07/2007	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Muscle protein turnover

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

Overall study start date
01/04/1997

Completion date
31/12/1998

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

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)

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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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