

Randomised controlled trial of the benefits of oral essential amino acids in haemodialysis patients at high risk for hospitalisation

Submission date
13/09/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
25/10/2006

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
25/10/2006

Condition category
Urological and Genital Diseases

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

CT 00-AMI-003

Study information

Scientific Title

Study objectives

Can health parameters be improved in patients on maintenance haemodialysis by oral supplementation with essential amino acids?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Western Institutional Review Board (USA) approved on 27 November 2002 (Study number: 1033247, Invest. number: 67275).

Primary study design

Interventional

Study design

Randomised, multicentre, double-blind, parallel, placebo-controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

End Stage Renal Disease (ESRD), and haemodialysis

Interventions

Essential amino acid supplementation/placebo treatment in haemodialysis patient for six months or until a primary end-point is reached.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Essential amino acid supplementation

Primary outcome(s)

The primary outcome was comparing the time of the composite primary outcome of :

1. Hospitalisation, other than for uncomplicated dialysis access procedure
2. Prolonged Emergency Room (ER) visit (more than 16 hours)
3. Out of hospital death

Key secondary outcome(s)

Secondary efficacy analyses, for the following outcomes comparing the change in the given parameter from baseline to the last available study measurement:

1. Change in subjective global assessment
2. Change in grip strength
3. Change in quality of life measures (using Short Form 12 instrument)
4. Change in lowest post dialysis weight

Completion date

20/01/2006

Eligibility

Key inclusion criteria

1. Patients on maintenance haemodialysis for at least four months at high risk of hospitalisation. This is defined as:

- a. no more than two weeks post discharge from an acute hospitalisation and a serum albumin below 4.0 g/dl
- b. a serum albumin below 3.8 g/dl

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Patients who have difficulties in taking pills, due to problems swallowing or intractable vomiting
- 2. Patients who have a short time life expectancy or are awaiting non-cadaveric kidney transplantation

Date of first enrolment

09/01/2003

Date of final enrolment

20/01/2006

Locations

Countries of recruitment

Ireland

United States of America

Study participating centre

Department of Nephrology

Cork

Ireland

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Sponsor information

Organisation

Recip AB (Sweden)

ROR

<https://ror.org/01apnjb23>

Funder(s)

Funder type

Government

Funder Name

National Institute of Diabetes and Digestive and Kidney diseases (NIDDK), National Institutes of Health (USA)

Funder Name

Recip AB (Sweden)

Funder Name

Gambro Corporate Research

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration