ISRCTN21593740 https://doi.org/10.1186/ISRCTN21593740

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

Submission date	Recruitment status	[_] Prospectively registered
13/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2006	Urological and Genital Diseases	[_] Record updated in last year

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
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).

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
09/01/2003

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

Age group
Adult

Sex
Both

Target number of participants
Patients planned for approximately 400. Patients obtained 84

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)

Sponsor details
Lagervägen 7
Haninge
Sweden
SE -136 50

Sponsor type
Industry

Website
http:// www.recip.se

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

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