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The efficacy of disease-specific nutritional support compared with usual treatment in hemodialysis patients

Submission date 19/07/2006	**Recruitment status** No longer recruiting
Registration date 19/07/2006	**Overall study status** Completed
Last Edited 08/01/2021	**Condition category** Urological and Genital Diseases

[_] 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
100059, NL638, NTR698

Study information

Scientific Title
The efficacy of disease-specific nutritional support compared with usual treatment in hemodialysis patients

Acronym
Renilon 7.5 study.

Study objectives
The nutritional status of patients supplemented with Renilon 7.5 for three months will be improved compared with patients who receive the standard treatment. Nutritional status will be assessed by a significant improvement after three months of treatment by the following parameters: normalized protein catabolic rate (nPCR), serum albumin, serum pre-albumin, serum creatinine and dry-body weight.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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 disease

Interventions
Duration of intervention: three months.
Intervention group: standard therapy and in addition, a daily nutritional energy-dense (2 kcal/ml) supplement containing 7.5 g/100ml of demineralised whey protein and very low amount of minerals (especially phosphate) which provides 500 kcal of energy and 18.8 gram protein.
Control group: all subjects in the control group received standard therapy.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Renilon 7.5

Primary outcome measure
Nutritional status as assessed by:
1. nPCR
2. Serum albumin
3. Serum pre-albumin
4. Serum creatinine
5. Dry body weight.

Secondary outcome measures
1. Phosphate binder use
2. Quality of life
3. Dietary intake
4. Blood parameters
5. Nutritional status as assessed by subjective global assessment (SGA)

Overall study start date
01/09/2003

Completion date
01/09/2005

Eligibility

Key inclusion criteria
End-stage renal disease patients on hemodialysis treatment:
1. Requiring thrice-weekly hemodialysis for at least three months
2. Stable disease (no recent hospitalizations except for minor access-related stays)
3. C-reactive protein <20 mg/l
4. nPCR <1.0
5. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
88

Total final enrolment
86

Key exclusion criteria
1. Inadequate dialysis (Kt/V <1.2)
2. Peritoneal dialysis in the last three months
3. Serum albumin >40 g/l
4. Body mass index (BMI) >30 kg/m^2
5. Use of any investigational drug
6. Nutritional supplementation within the last two months
7. Requiring complete enteral nutrition
8. Age <18 years

Date of first enrolment
01/09/2003

Date of final enrolment
01/09/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Numico Research B.V.,
Wageningen
Netherlands
6700 CA

Sponsor information

Organisation
Numico Research B.V. (The Netherlands)

Sponsor details
P.O. Box 7005
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6700 CA

Sponsor type
Industry

ROR

https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research B.V.

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	01/09/2008	08/01/2021	Yes	No