

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

Submission date

19/07/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

19/07/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

08/01/2021

Condition category

Urological and Genital Diseases

☐ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

Nutritional status as assessed by:

1. nPCR

2. Serum albumin
3. Serum pre-albumin
4. Serum creatinine
5. Dry body weight.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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/m²
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)

ROR

<https://ror.org/00aj77a24>

Funder(s)

Funder type

Industry

Funder Name

Numico Research B.V.

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