The efficacy of disease specific nutritional support compared with usual treatment in hemodialysis (HD) patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29108

Source
Nationaal Trial Register

Brief title
Renilon 7.5 study.

Health condition

End stage renal disease patients on hemodialysis.

Sponsors and support

Primary sponsor: Numico Research B.V.
Source(s) of monetary or material Support: Numico Research B.V.

Intervention

Outcome measures

Primary outcome

Nutritional status as assessed by nPCR, serum albumin, serum pre-albumin, serum creatinine, and dry body weight.

Secondary outcome

Phosphate binder use, Quality of Life, dietary intake and blood parameters. Nutritional status as assessed by SGA.

Study description

Background summary

Renilon 7.5 was developed to provide HD patients with adequate energy and protein with very low amounts of minerals. HD patients with a low protein intake were randomized in this controlled parallel design study to use the test product for an intervention period of 3 months. Nutritional status, phosphate binder use, Quality of Life, dietary intake and blood parameters were evaluated at regular intervals throughout the intervention period.

Study objective

The nutritional status of patients supplemented with Renilon 7.5 for 3 months will be improved compared with patients who receive the standard treatment. Nutritional status will be assessed by a significant improvement after 3 months of treatment by the following parameters: nPCR, serum albumin, serum pre-albumin, serum creatinine or dry-body weight.

Study design

N/A

Intervention

Duration intervention: 3 Months.

Intervention group: Standard therapy and additionally daily a nutritional energy dense (2kcal/ml) supplement containing 7.5 g/100ml of demineralised whey protein and very low amounts 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.

Contacts

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Eligibility criteria

Inclusion criteria

End-stage renal disease patients on hemodialysis treatment:

1. requiring thrice weekly hemodialysis for at least 3 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.

Exclusion criteria

1. Inadequate dialysis (Kt/V < 1.2);

2. peritoneal dialysis in the last three months;

3. serum albumin > 40 g/L;

4. 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2003
Enrollment:	88
Type:	Actual

Ethics review

Positive opinion

Date:	06-06-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL638
NTR-old	NTR698
Other	: Protocol Number 100059
ISRCTN	ISRCTN56882109

Study results

Summary results
Nephrol Dial Transplant. 2008 Sep;23(9):2902-10. Epub 2008 Apr 11.