

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	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

### Public

Numico Research B.V.,  
PO Box 7005

Jane McKenzie  
Wageningen 6700 CA  
The Netherlands  
+31 (0)317 467800  
**Scientific**  
Numico Research B.V.,  
PO Box 7005  
Jane McKenzie  
Wageningen 6700 CA  
The Netherlands  
+31 (0)317 467800

## 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/m<sup>2</sup>;
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.