

# 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

**Contact name**

Ms Jane McKenzie

**Contact details**

Numico Research B.V.,

PO Box 7005

Wageningen

Netherlands

6700 CA

+31 (0)317 467800

Jane.McKenzie@Numico-Research.nl

## 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/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

**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?
<a href="#">Results article</a>	results	01/09/2008	08/01/2021	Yes	No