

# Metabolic effects of two low protein diets in chronic kidney disease stage four to five: a randomised controlled trial

**Submission date**

26/02/2007

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

14/06/2007

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

09/05/2019

**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**

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## Additional identifiers

**Protocol serial number**

00138

## Study information

**Scientific Title**

Metabolic effects of two low protein diets in chronic kidney disease stage four to five: a randomised controlled trial

**Study objectives**

To test the best metabolic control of renal failure with a low protein diet.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval received from the ethics board of the University of Naples on the 15th April 1998 (ref: 29/98).

**Study design**

Randomised, active controlled, parallel group trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Nephrology; chronic kidney disease, renal failure, uraemia

**Interventions**

Two diets with different protein content: 0.55 g/kg/day versus 0.80 g/kg/day.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Blood levels of urea

**Key secondary outcome(s))**

1. Plasma/serum levels of phosphate
2. Parathyroid hormone
3. Bicarbonate levels

**Completion date**

31/12/2002

**Eligibility****Key inclusion criteria**

1. Age of 18 years
2. A basal value of estimated Glomerular Filtration Rate (eGFR) equal or less than 30 ml/min/1.73 m<sup>2</sup>
3. After a three months baseline period the patients with stable renal function were deemed eligible for study

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Not Specified

**Total final enrolment**

423

**Key exclusion criteria**

1. Unstable renal function
2. Malignant disease, if treated with immunosuppressant drugs, or urinary protein excretion exceeding 5 g/24 hours
3. Pregnancy

**Date of first enrolment**

01/01/1999

**Date of final enrolment**

31/12/2002

**Locations****Countries of recruitment**

Italy

**Study participating centre**

University Federico II of Naples

Naples

Italy

80131

# Sponsor information

## Organisation

University Federico II of Naples (Italy)

## ROR

<https://ror.org/05290cv24>

# Funder(s)

## Funder type

Government

## Funder Name

Partially funded in an unrestricted manner by the Plans of Important National Interest (Progetti di Rilevante Interesse Nazionale) (PRIN) - 2001(ref: 061427) of the Italian Ministry of Universities (Italy)

# 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	01/02/2008	09/05/2019	Yes	No
<a href="#">Results article</a>	results	01/12/2009	09/05/2019	Yes	No