

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

Prof Bruno Cianciaruso

Contact details

University Federico II of Naples

Division of Nephrology

Building N°5

Via S. Pansini N°5

Naples

Italy

80131

-

cianciar@unina.it

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).

Primary study design

Interventional

Study design

Randomised, active controlled, parallel group trial

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 m²
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?
Results article	results	01/02/2008	09/05/2019	Yes	No
Results article	results	01/12/2009	09/05/2019	Yes	No