

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Blood levels of urea

Secondary outcome measures

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

Overall study start date

01/01/1999

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

420

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)

Sponsor details

School of Medicine

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Sponsor type

University/education

Website

<http://www.unina.it/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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