

Effects of dietary protein restriction on albumin and fibrinogen synthesis in macroalbuminuric Diabetes Mellitus type 2 (DM2) subjects

Submission date
06/09/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
19/11/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
10/06/2021

Condition category
Nutritional, Metabolic, Endocrine

☐ 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

diab-07-0804

Study information

Scientific Title

Effects of dietary protein restriction on albumin and fibrinogen synthesis in macroalbuminuric Diabetes Mellitus type 2 (DM2) subjects

Acronym

DM2LPD study

Study objectives

Dietary protein restriction on albumin and fibrinogen synthesis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethics committee of Second University of Naples (Comitato Etico Azienda Ospedaliera Universitaria - SUN) in 2005.

Study design

Interventional, randomised prospective clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes mellitus and nephropathy

Interventions

We compared the effects of a Normal Protein Diet (NPD) (1.38 ± 0.08 g/kg/day) or a Low Protein Diet (LPD) (0.81 ± 0.04 g/kg/day) on Endogenous Leucine Flux (ELF), albumin and fibrinogen synthesis (5,5,5-D₃-L-leucine infusion), and markers of inflammation, in 9 subjects with DM2 and macroalbuminuria.

The duration of treatment is 4 weeks pre-LPD and 4 weeks post-LPD. The total duration of follow-up for all treatment arms is 8 weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Albumin and fibrinogen synthesis, measured at baseline and four weeks pre-LPD and post-LPD.

Key secondary outcome(s)

Proteinuria and low-grade inflammation, measured at baseline and four weeks pre-LPD and post-LPD.

Completion date

07/07/2006

Eligibility

Key inclusion criteria

Eligibility criteria of type 2 diabetic patients included:

1. Body Mass Index (BMI) less than 35 kg/m²
2. Proteinuria greater than 3 g/day
3. Absence of urinary tract infection or other renal diseases

Age range and gender of our participants are:

1. DM2 (60 ± 2 years): 6 males, 3 females
2. Control (37 ± 3 years): 3 males and 3 females

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

15

Key exclusion criteria

Exclusion criteria of type 2 diabetic patients included:

1. BMI greater than 35 kg/m²
2. Proteinuria less than 3 g/day

Date of first enrolment

05/01/2005

Date of final enrolment

07/07/2006

Locations

Countries of recruitment

Italy

Study participating centre

Pzza L. Miraglia, 2

Naples

Italy

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Sponsor information

Organisation

Second University of Naples (Seconda Universita degli studi di Napoli) (Italy)

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Second University of Naples (Seconda Universita degli studi di Napoli) (Italy) - Department of Geriatrics and Metabolism Diseases

Funder Name

Italian Ministry for University and Scientific Research (MIUR) (Italy) (ref: PRIN prot. 2004060902_005)

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		01/01/2008	10/06/2021	Yes	No