

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

05/01/2005

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

Age group

Adult

Sex

Both

Target number of participants

10

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

Pizza L. Miraglia, 2

Naples

Italy

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Sponsor information

Organisation

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

Sponsor details

Department of Geriatrics and Metabolism Diseases

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Sponsor type

University/education

Website

<http://web.unina2.it/>

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Second University of Naples (Seconda Università 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

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