Use of monomeric and oligomeric flavanols in the dietary management of patients with type 2 diabetes and microalbuminuria

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20416

Source
NTR

Brief title
FLAVA-trial

Health condition

Diabetes type 2, microalbuminuria

Sponsors and support

Primary sponsor: Erasmus Medical Center, Department of Internal Medicine
Source(s) of monetary or material Support: International Nutrition Company BV (INC BV), Loosdrecht, The Netherlands

MULTICENTER TRIAL: Erasmus Medical Center in Rotterdam and the community hospitals: Havenziekenhuis, IJsselland Ziekenhuis and Ikazia Ziekenhuis as well as GP-clinic Stichting Gezond op Zuid in Rotterdam.

Intervention

Outcome measures

Primary outcome

Renal endothelial function will be measured before, during and after the intervention using albumin excretion rate in 24h urine (AER)

Secondary outcome

Established plasma biomarkers for renal endothelial function, namely asymmetric dimethylarginine (ADMA), vascular cell adhesion molecule 1 (VCAM-1), interleukin 6 (IL-6), von Willebrand Factor (vWF) and intercellular cell adhesion molecule 1 (ICAM-1).

Study description

Background summary

-

Study objective

We hypothesize that monomeric and oligomeric flavanols (MOF) have a beneficial effect on renal-endothelial function in the dietary management of T2D, as reflected by improvement of AER and renal-endothelial biomarkers.

Study design

baseline - 6 weeks - 3 months

Intervention

During 3 consecutive months, the intervention group receives 200 mg of MOF once daily in the form of a commercially available Food for Special Medical Purposes (Endoclair), whereas the control group receives a placebo once a day

Contacts

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Eligibility criteria

Inclusion criteria

• T2D
• Age 40-85 years
• Microalbuminuria in the previous 6 months (as microalbuminuria can change during time, results shouldn’t be older than 6 months), defined as:
- 30-300 mg albumin in a 24-hour urine sample
- or 3.5-35 mg albumin/mmol creatinine in females and 2.5-25 mg albumin/mmol creatinine in males in a urine portion.
This definition is derived from the Dutch national guidelines.

Exclusion criteria

• Other types of diabetes mellitus as derived from the medical records
• Prior (less than 4 weeks before participating) or current use of any specific dietary supplementary products providing daily amounts of MOF of 25 mg/day or higher
• Anticoagulation medication
• Major health conditions: organ transplantation, untreated cancer, current chemotherapy or radiotherapy, acute or chronic organ failure
• Microalbuminuria due to other conditions than T2D
• Pregnancy or lactation during the trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	96
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-07-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4534
NTR-old	NTR4669
Other	METC Erasmus MC : MEC-2014-426

Study results