The relationship between protein intake, gut microbiota and type 2 diabetes in subject with varying ethnic backgrounds

No registrations found.

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

Summary

ID

NL-OMON27966

Source
NTR

Brief title
MICRODIET

Health condition

Type 2 diabetes

Sponsors and support

Primary sponsor: Amsterdam Medical Center (AMC)
Source(s) of monetary or material Support: Leduq foundation and JPI

Intervention

Outcome measures

Primary outcome

- Post-prandial glycemic excursion (Area Under the Curve (AUC)) after a MMT and by continuous glucose monitors at baseline and after a three months dietary intervention in T2D patients from Caucasians and Caribbean background.

Secondary outcome

- Changes in oral and fecal microbiota composition as well as (postprandial) plasma metabolites (e.g. ImP, TMAO) at baseline and after a three months dietary intervention in T2D patients from Caucasians and Caribbean background.

-Body weight en body composition at baseline and after three months of dietary intervention in T2D patients from Caucasians and Caribbean background.

- The influence of baseline gut microbiota divesity in Caribbean subjects on (postprandial) glucose response after a three months of (high or low) protein diet.

- The impact of a high or low protein diet on quality of life of T2D patients from Caucasians and Caribbean background, as determined via questionaires.

- The impact of a high or low protein diet on gastro-intestinal complaints of T2D patients from Caucasians and Caribbean background, as determined via questionaires.

- The impact of a high or low protein dietary intervention on eating patterns and physical activity of T2D patients from Caucasians and Caribbean background, as determined via questionaires.

Study description

Background summary

Objective: To study the effects of a high protein (HP) vs low protein (LP) diet on gut microbiota composition and production of pro-diabetic metabolites in type 2 diabetes (T2D) patients from Caucasian and Carribean ethnicity.

Rationale: The gut microbiota is thought to play a pivotal role in the pathophysiology of cardio-metabolic diseases (CMD), such as T2D, obesity and atherosclerosis(1–3). The gut microbiota itself is strongly influenced by diet and ethnicity (4–6).However, most dietary studies have focussed on the role of carbohydrate/ fat intake and studies investigating the role of dietary protein and gut microbiota composition are scarce. These studies are needed since preliminary results from our group show that imidazole propionate (ImP), a degradation product of the essential amino acid histidine, is produced by the gut microbiota of T2D patients, but not healthy subjects. We hypothesize that increased protein intake in T2D subjects will lead to an increased production of pro-diabetic metabolites, such as ImP, and higher plasma glucose levels. We also hypothesize that in some ethnic groups this effect is larger due to a reduced microbial diversity.

Study design: Randomized controlled three months dietary intervention study

Study Population: T2D patients from Caucasian (N=40) and Caribbean (N=80) background who are on a stable dose of metformin and do not use insulin or proton-pump inhibitors.

Intervention: Subjects will be randomized to either a high protein (HP) or low protein (LP) diet for three month. Individuals of Caribbean ethnicity, will also be stratified according to either a high or low gut microbiota gene richness. All subjects will receive pre-cooked meals 6 days per week and daily food packages. Subjects are required to keep food diaries three days a week and will also have weekly contact with an AMC dietician.

Outcome measures: Primary endpoints are changes in glycemic excursion after a mixed meal test at baseline and after 12 weeks. Furthermore we will determine oral and fecal microbiota composition and plasma levels of intestinal metabolites, such as ImP, body weight and body composition at baseline and after 12 weeks.

Sample Size: It is calculated that a total of 20 patients per arm are needed.

Study objective

A high protein intake will lead to high histidine intake and subsequently increased production of Imidazole Propionate, which will increase insulin resistance.

Study design

3 month dietary intervention with visits at week 0, week 6 and week 12.

Intervention

Dietary intervention study, randomized between a high protein VS a low protein group.

Contacts

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Eligibility criteria

Inclusion criteria

- Age between 40-70 years

- Presence of T2D

- BMI≥25kg/m2

- Use of metformin on a stable dose (i.e. no changes in the last three months)

- Adequate knowledge of the Dutch language to comprehend the provided study information

Exclusion criteria

- Use of insulin

- Use of a proton-pump inhibitor

- Use of antibiotics 3 months before inclusion

- Use of pro- or prebiotics

- Vegetarian diet

- Presence of inflammatory bowel disease or other chronic inflammatory disease

- More than 5 units of alcohol consumption per week

- Active malignancy

- bariatric or other weight loss surgery in the history

- patients diagnosed with eating disorders (such as bulimia nervosa, anorexia nervosa or binge-eating disorder)

- HbA1c >9% (75mmol/mol)

- Unmotivated or not able to adhere to a specific diet.

- Estimated glomerular filtration (eGFR) < 50ml/min/1.73m2

- The subject is already involved in a clinical trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2018
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-08-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48642
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7226
NTR-old	NTR7424
CCMO	NL65782.018.18
OMON	NL-OMON48642

Study results