Effect of oral Curcumin on Gut Microbiota Composition in patients with Diabetes Type II, Ulcerative Colitis, Crohn's disease and healthy subjects

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26278

Source Nationaal Trial Register

Brief title Curcumin Microbioom

Health condition

Diabetes Mellitus Type 2, Crohn's disease, Colitis Ulcerosa and healthy volunteers

Sponsors and support

Primary sponsor: none Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The primary outcomes is to investigate changes in the composition of gut microbiota and the

1 - Effect of oral Curcumin on Gut Microbiota Composition in patients with Diabetes ... 26-06-2025

measurable outcomes of this change in composition.

Secondary outcome

- Fecal gutmicrobiota composition (as determined by 16S sequencing) at these three timepoints

- changes in fecal SCFA metabolites at these three timepoints

- the fecal, urine and plasma (gutmicrobiota derived) curcumin metabolites at these three timepoints

- changes in Continuous Glucose Monitoring (CGM, Free Style Libre) before and at end of study. Also, fasting glucose, insulin levels, HOMA, Hba1c, lipid profile including LDL-cholesterol (diabetes type II patients) will be studied

- disease changes in SSCAI and HBI scores (ulcerative colitis and Crohn's disease) and changes in fecal calprotectin

- Changes in the inflammatory response by assessing the changes in levels of inflammatory markers (IL-1,-2,-6,-8 and -12, tumor necrosis factor-alpha (TNF-a), monocyte chemoattractant protein-1, LPS binding protein (LPB)

- Changes in enzymes involved in the inflammatory response such as inducible nitric oxide synthase (iNOS), cyclooxygenase-2 (COX-2), lipoxygenase and xanthine oxidase activity)

Study description

Background summary

To investigate the effect of oral curcumin supplementation on the gut microbiota composition in patients with diabetes type II, inflammatory bowel disorders (both ulcerative colitis and Crohn's disease) and healthy subjects.

Study objective

Curcumin is expected to have a positive effect in the composition of gut microbiota and the measurable outcomes of this change in composition.

Study design

t=0 weeks, t=4 weeks and t=8 weeks

Intervention

6 g Curcumin / day for 8 weeks

Contacts

Public Amsterdam UMC, location AMC Maurice Kroon

020-5661425 **Scientific** Amsterdam UMC, location AMC Maurice Kroon

020-5661425

Eligibility criteria

Inclusion criteria

- Aged 18-65 years
- Stable therapy (i.e. no major dosage changes in the last three months)
- Able to give written informed consent

Exclusion criteria

- Tobacco use (as there are indications this influences the gut microbiota, Huang et al. 2019)
- Alcohol use > 1 units/day,
- Excessive weight loss of >10% in the last 3 months,
- Levels of plasma aspartate aminotransferase (ASAT) and alanine aminotransferase (ALAT)
- 2.5 times or more the upper limit of the normal range,
- Other liver abnormalities,
- Known intolerance to curcumin or curcumin-derivatives,
- Use of food supplements containing curcumin or/and black pepper for at least 3 days prior to each study day and two weeks prior to the study,
- Daily use of non-steroidal anti-inflammatory drugs (NSAIDS),
- Use of proton pump inhibitors (as this influences intestinal microbiota composition)
- Eating/drinking of grapefruit and grapefruit-containing products or star fruit during the course of the study,
- Incomplete information or unwillingness to comply with the intervention,

- Participation in other intervention studies 3 months before or after the duration of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2020
Enrollment:	40
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable Application type:

Not applicable

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.

4 - Effect of oral Curcumin on Gut Microbiota Composition in patients with Diabetes ... 26-06-2025

In other registers

Register

NTR-new Other **ID** NL8770 METC AMC : 2020-155

Study results