The effect of dried chicory root on inflammation, gut microbiota and complaints in patients with Inflammatory Bowel Disease: a pilot study

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Primary Objective: To explore the effect of a 4-week 10-20 g/day WholeFiberTM intervention on fecal calprotectin levels in patients with CD and UC.Secondary Objective(s):- To explore the effect of a 4-week WholeFiberTM intervention on stool pattern...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON56552

Source
ToetsingOnline

Brief title
Chicory fiber in IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, IBD

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: KIEM.K23.01.148 ,MyMicroZoo Mkb onderneming,WholeFiber INC,levert product gratis; draagt verder niet financieel bij (MKB)

Intervention

Keyword: dietary fibre, gut microbiome, IBD (inflammatory bowel disease), inflammation

Outcome measures

Primary outcome

Primary Objective:

To explore the effect of a 4-week 10-20 g/day WholeFiberTM intervention on

fecal calprotectin levels in patients with CD and UC.

Secondary outcome

Secondary Objective(s):

- To explore the effect of a 4-week WholeFiberTM intervention on stool pattern,

IBD-complaints and QoL in patients with CD and UC.

- To explore the effect of a 4-week WholeFiberTM intervention on fecal

microbiota composition, SCFA levels, fecal pH and redox status in patients with

CD and UC.

- To explore the effect of a 4-week WholeFiberTM intervention on serum markers

in IBD in patients with CD and UC.

- How is the use of WholeFiberTM evaluated by patients with CD and UC?

- Is there a difference in effect of WholeFiberTM between patients with CD and

UC?

Study description

Background summary

Dietary fiber intake is usually lower than recommended and dried vegeltable can be a useful additional source. This may inprove the gut microbiome, increase SCFA production and reduce inflammation

Study objective

Primary Objective:
To explore the effect of a 4-week 10-20 g/day WholeFiberTM intervention on fecal calprotectin levels in patients with CD and UC.

Secondary Objective(s):
- To explore the effect of a 4-week WholeFiberTM intervention on stool pattern, IBD-complaints and QoL in patients with CD and UC.
- To explore the effect of a 4-week WholeFiberTM intervention on fecal microbiota composition, SCFA levels, fecal pH and redox status in patients with CD and UC.
- To explore the effect of a 4-week WholeFiberTM intervention on serum markers in IBD in patients with CD and UC.
- How is the use of WholeFiberTM evaluated by patients with CD and UC?
- Is there a difference in effect of WholeFiberTM between patients with CD and UC?

Study design

This is a 4-week before-after pilot study to explore the effectiveness of a WholeFiberTM intervention (a dried vegetable rich in prebiotic intrinsic fibers) on inflammation, fecal gut microbiota and metabolites, IBD-complaints and QoL and assesses its feasibility. In this before-after study, 12 patients with IBD will receive WholeFiberTM; of which 6 patients with CD and 6 patients with UC to assess if there is a difference in effect between these groups of patients.

Since a sudden increase in dietary fiber can cause some changes in GI-related sensations, such as bloating, flatulence, belching and nausea (Reynolds et al., 2020), fiber intake will be gradually increased in this trial. First, subjects will receive 10 g/day of WholeFiberTM (~8.5 g/day of fiber) for the first 2 weeks, after which they will increase the dose to 2x 10 g/day of WholeFiberTM (~17 g/day of fiber) for the last two weeks. y.

There are three timepoints included in this study:
- At the start (baseline), where patients will take a fecal sample, a blood sample will be drawn and patients will fill in questionnaires.
- Halfway (after 2 weeks), patients will fill in online questionnaires at home.
- At the end (after 4 weeks), patients will take a fecal sample, a blood sample will be drawn and patients will fill in questionnaires.

Intervention

Terwijl patiënten hun gebruikelijke voeding blijven eten krijgen ze in de eerste 2 weken van de interventie 10 gram Whole Fibre per dag. In de derde en vierde week is dit 20 gram Whole Fibre per dag.
While patients keep following their habitual dietary intake, they will consume 10 gram of Whole Fiber during the first two weeks and 20 gram of Whole Fibre during week 3 and 4.

Study burden and risks

The intervention is therapeutic for the paticipants. The risj associated with the particpation is neglible and the burden can be considered as minimal.
During both visits:
3 tube of bood will be drawn (28 ml per time: totaal 56 ml during the complete study)
Participants will be asked to consume extra 10 gram of Whole fibre during the first 2 weeks; during week 3 and week 4 they will be asked to consume 20 gram Whole Fibre (a vegetable fibre)
3 times they will be asked to complete questionnaires, which will not cause psychological damage. The following questionnaires will be used:Er wordt HBI or SSCAI vragenlijst, FrQOL, Bristol stool chart)
They will be asked to fill out a 3 day food diary twice.
Twice fecal samples will be collected, which will be collected from their home
Total length of the study for a participant is 4 weeks, total time involved is 3.5 hours

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Men and women aged >=18 years;
- Having a diagnosis of IBD (either UC or CD) and undergoing treatment at the outpatient at UMCG;
- Mild or moderate IBD, defined as fecal calprotectin levels >=100 µg/ gram faeces and Harvey Bradshaw Index (HBI) <8 for CD patients or Simple Clinical Colitis Activity Index (SCCAI) <5 for CU patients;
- Using stable maintenance therapy for at least 12 weeks;
- Being able to read and speak Dutch;
- Willing to come to the UMCG for practical reasons (visiting the study site);
- Willing to continue their regular lifestyle patterns during the study.

Exclusion criteria

- Having a medical history that may impact study outcomes, such as a diagnosis of diabetes mellitus type 2, heart disease, renal disease, cancer, celiac disease;
- Having an ileostomy or colostomy, as this greatly impacts bowel function and gut microbiota composition;
- Having a clinically significant stenosis;
- Use of antibiotics <4 weeks before study start;
- Use of prebiotics, probiotics and/or synbiotics (this should be stopped 4 weeks before start of the study) or other fiber supplements such as psyllium;
- Use of tube feeding or sib-feeding;
- Being pregnant or lactating;
- Participation in another clinical study at the same time;
- Unable or unwilling to comply to study rules.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2024
Enrollment:	12
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	20-02-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT06016322
CCMO	NL85061.042.23