Measuring effects of high-fiber dried chicory root on the gut microbiota of patients with an intermediate to high-risk cutaneous melanoma: an explorative study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin neoplasms malignant and unspecified
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57206

Source
ToetsingOnline

Brief title
MELFIB

Condition

- Skin neoplasms malignant and unspecified

Synonym
Cutaneous melanoma skin cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van OC&W aan universiteiten)

Intervention

- Food (substances)

Keyword: cutaneous melanoma, dried chicory root, gut microbiota, high-fiber

Explanation

N.a.

Outcome measures

Primary outcome

Effect of a high fiber prebiotic vegetable (WholeFiber) for 6 weeks on fecal
SCFA levels in intermediate to high-risk cutaneous melanoma patients, with no
concurrent adjuvant treatment. HPLC ion chromatography system (Metrohm AG,
Herisau, Switzerland) will be used to determine the levels of SCFA. The
concentrations of SCFA; butyrate, propionate, and acetate will be measured with
a conductivity detector. SCFA will be measured at baseline, halfway
intervention and after 6 weeks.

Secondary outcome

Discovering the gut microbial composition changes measured in intermediate to
high-risk cutaneous melanoma patients with no concurrent adjuvant treatment,
after using WholeFiber for 6 weeks. This analysis will be based on whole genome
sequencing of fecal samples performed at the UMCG according to standardized
protocol.
Exploring the effect of WholeFiber use for 6 weeks on immune functioning, stool
patterns, fecal calprotectin levels and side effects in this patient group.
Peripheral blood mononuclear cells (PBMCs) and bloodplasma will be isolated to
be able to identify hypothesized changes in immune cell composition. Fecal
calprotectin will be determined using the respective ELISA kit (Thermo Fisher
Scientific). Calprotectin is released when neutrophils enter the gut wall and
are activated during the inflammatory process. Lastly, eating patterns, fiber
intake before the start of the studyperiod, stool patterns and side effects
will be identified using
- Food Frequency Questionnaire
- Bristol Stool Scale
- Gastrointestinal Symptoms Rating Scale

- Health Related Quality of Life Questionnaire</p>

Study description

Background summary

After surgical treatment of an intermediate to high-risk cutaneous melanoma (T3/T4), recurrence can take place within 5 years in around 30-50% of the cases. The gut microbiome, consisting of bacteria and other microorganisms living in the gut, has been identified as therapeutic target in patients with stage IV melanoma treated with immune checkpoint inhibition. Interestingly, in intermediate to high-risk cutaneous melanoma (minimal stage II A) very often tumor infiltrating lymphocytes are found, which sometimes leads to spontaneous remission of these tumors. Therefore, it can be beneficial to explore the gut microbial composition and modulatory capacity of the gut microbiome in this patient group to see whether the gut microbiome could play a role in strengthening immune system functioning. Dietary fibers can modulate the gut microbial composition, thereby favoring bacteria which are able to produce short-chain fatty acids (SCFAs). These SCFAs are hypothesized to have a beneficial effect on the immune cell composition, fecal calprotectin levels, stool pattern and general well-being.

Study objective

The primary objective of this study is to investigate the effect of dried chicory root (WholeFiber) during 6 weeks on fecal SCFA levels in intermediate to high-risk melanoma patients after surgical treatment with no concurrent adjuvant treatment.

Secondary objectives
• Analysis of the gut microbial composition of surgically treated intermediate to high-risk cutaneous melanoma patients before intake and potential compositional changes after using WholeFiber for 6 weeks.
• Exploration of the effect of WholeFiber use for 6 weeks on immune cell composition, stool patterns, fecal calprotectin levels and side effects in intermediate to high-risk cutaneous melanoma patients after surgical treatment, with no concurrent adjuvant treatment.

Study design

This study will be an explorative study at the University Medical Center Groningen (UMCG). All measurements, in detail described in chapter *8.3 - Study procedures*, will be performed in all patients. The effect of oral intake of dried chicory root (WholeFiber) in intermediate to high-risk cutaneous melanoma

after surgical treatment, with no concurrent adjuvant treatment, will be tested. Inclusion of patients in the study can take place within 16 weeks after surgery, the baseline visit (T0) can take place later than 16 weeks after surgery. This is in line with the exclusion criterium that patients can't use antibiotics in the 3 months prior tot inclusion. WholeFiber will be used by the patients for 6 weeks two times a day (10 g per portion). In the first week of the intervention WholeFiberTM will be used one time a day (10 g per portion) to let the study participants adjust to the product. The study consists of 4 visits, including the informed consent visit. The estimated visit time is 60 minutes, apart from the inclusion
visit which will take approximately 30 minutes.

Three timepoints are included in this study:
• Baseline (T0), where patients will collect a fecal sample at home, a blood sample will be drawn, and patients will fill in questionnaires.
• Mid-Trial (T1), collection of a fecal sample at home, a blood sample will be drawn, and patients will fill in questionnaires.
• End of Trial (T2), collection of a fecal sample at home, a blood sample will be drawn, and patients will fill in questionnaires.

Intervention

Subjects will receive 2 sachets of 10 g WholeFiber per day for 6 weeks (equals 17 g fiber). In the first week the dose will be 10 g/day, to get used to the product.

Study burden and risks

WholeFiber is a dried vegetable (chicory root) that for 85% consists of prebiotic fibers, safe for consumption and is commercially available. Increasing dietary fiber intake is beneficial for overall health and may give some abdominal complaints at the start of use. Patients will visit the study site three times for blood tests and fecal samples will be collected at home. Filling in questionnaires is also a burden.

Contacts

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Trial sites

Trial sites in the Netherlands

Universitair Medisch Centrum Groningen
Target size: 20

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >=18 years;
• The participant understands the study and can provide written informed consent;
• The participant received surgical treatment of an intermediate to high-risk cutaneous melanoma (T2a, T2b, T3a, T3b, T4a, T4b, N0 or N+, M0, Stage IV with no evidence
of M+ disease);
• 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

• Receiving concurrent adjuvant treatment, adjuvant treatment after the study

period is allowed.
• Having a medical history that may impact study outcomes, such as a diagnosis of diabetes mellitus type 2, heart disease, renal disease, autoimmune disease;
• Any clinically significant or unstable medical disorder involving the gut, including celiac disease, inflammatory bowel disease, short-bowel syndrome or acute/chronic pancreatitis;
• Having an ileostomy or colostomy, as this greatly impacts bowel function and gut microbial composition;
• Use of antibiotics in the 3 months prior participation in the study;
• Use of prednisolone or other immunosuppressive medication;
• Use of tube feeding or sib-feeding;
• Being pregnant or lactating;
• Participation in another interventional study at the same time;
• Unable or unwilling to comply to study rules.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-03-2025
Enrollment:	20
Duration:	2 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO Date:	09-12-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-06-2025
Application type:	Amendment
Review commission:	METC UMCG

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
CCMO	NL86967.042.24
Research portal	NL-005405