FiberUP in clinical practice

Published: 23-11-2023
Last updated: 30-11-2024

To investigate the feasibility of increasing preoperative dietary fiber intake in CRC patients undergoing surgery via 1) personalized dietary advice (Vezel-UP tool), or 2) vegetable product containing natural fibers (WholeFiber) compared to 3)...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON53209

Source
ToetsingOnline

Brief title
FiberUP

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Alliance TU/e WUR UU UMC Utrecht (EWUU);St. Alliantie Voeding in de Zorg

Intervention

Keyword: Colorectal cancer, Dietary fiber, Postoperative complications, Surgery

Outcome measures

Primary outcome

The primary outcome is the change in dietary fiber intake, which is assessed via two 24hr dietary recalls at baseline and during and after the intervention.

Secondary outcome

Secondary parameters are stool pattern, quality of life, fecal microbiota composition, fecal and plasma microbial metabolites levels (i.e., SCFA and indoles), and length of hospital stay. These secondary objectives will be included to generate preliminary (biological) data to support the design of a future intervention studies by further understanding the underlying biological mechanisms related to postoperative complications and provide necessary data for sample size calculations.

Study description

Background summary

Postoperative complications affect up to 50% of the colorectal cancer (CRC) patients undergoing surgery, and are associated with impaired quality of life and higher mortality rates. We have shown that higher preoperative dietary fiber intake is associated with a lower risk of postoperative complications. To follow-up on our previous observational study, we would like to investigate the potential causality of the relationship between dietary fiber and postoperative complications. However, it is yet unknown which method is effective and feasible for improving preoperative dietary fiber intake in CRC patients.

Study objective

To investigate the feasibility of increasing preoperative dietary fiber intake

in CRC patients undergoing surgery via 1) personalized dietary advice (Vezel-UP tool), or 2) vegetable product containing natural fibers (WholeFiber) compared to 3) habitual diet (control group).

Study design

A randomized controlled trial with three groups: 1) Vezel-UP group, 2) WholeFiber group, and 3) control group. The intervention period equals the time between diagnosis and surgery, which is on average ~4 weeks but will vary between individual patients depending on their characteristics (e.g., physical condition and tumor location) and waiting list.

Intervention

1) Vezel-UP group: subjects will receive personalized dietary advice (PDA) based on their habitual food pattern (as assessed using a food frequency questionnaire) and preferences. Based on a previously developed algorithm, the PDA provides fiber-rich alternatives for currently used low-fiber products, close to subjects* current eating behavior, to help increase dietary fiber intake. This PDA will be provided using an online web-portal.

2) WholeFiber group: subjects will consume 2 sachets with each 7.5 g of WholeFiberTM per day, which equals 12.3 g of dietary fiber per day. WholeFiberTM consists of dried cubes of chicory root. Subjects can choose when and how they consume WholeFiberTM, for example sprinkle it over their meal, or include in existing recipes.

3) control group: subjects will following their habitual diet during preoperatieve period.

Study burden and risks

This study has a negligible risk for subjects, as all advised fiber-rich products (Vezel-UP group) and the vegetable product (WholeFiber group) are commercially available and are deemed safe for consumption. Previous studies have shown that both methods of increasing dietary fiber intake were well tolerated by subjects in terms of abdominal complaints. Also, the burden of this study is limited as questionnaires and fecal sample collection can be completed at home. In most cases, visits to the hospitals for blood collection will coincide with an existing appointment in the hospital of this patient. This intervention study will not change in any way subjects* treatment for CRC.

Contacts

Public
Wageningen Universiteit

Stippeneng 4
Wageningen 6708 WE
NL
Scientific
Wageningen Universiteit

Stippeneng 4
Wageningen 6708 WE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult colorectal cancer patients who are recently diagnosed and planned to undergo elective resection to remove the tumor.

Exclusion criteria

A patient who meets any of the following criteria will be excluded from participation in this study:
• Previously have had a large abdominal resection, excluding appendectomy and cholecystectomy;
• Diagnosed with Crohn*s disease, Ulcerative Colitis, Coeliac Disease;
• Currently having a stoma;

• Known allergic reactions to plants from the Asteraceae (Compositae) family (e.g., lettuce, daisies, sunflowers, artichokes, sage, tarragon, chamomile, chicory etc.);
• Currently following a strict diet and unwilling or unable to change (e.g., gluten free or ketogenic diet);
• Currently using fiber supplements, prebiotics and/or probiotics and unwilling to stop using these for the duration of the intervention;
• Having a habitual dietary fiber intake >30 g/day for women and >40 g/day for men, measured with a food frequency questionnaire;
• Dementia or other cognitive disabilities that makes it impossible to fill out questionnaires correctly;
• Illiteracy (inability to read and understand Dutch).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-04-2024
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO

Date:	23-11-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	11-04-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT06212817
CCMO	NL84650.091.23