The perioperative microbiota composition in colorectal surgery patients receiving oral antibiotics or no oral antibiotics

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Primary Objective: Exploring peri-operative changes in microbiota composition between patient receiving oral antibiotics, oral antibiotics with amphotericin B or no oral prophylaxis, performed by 16S rRNA sequencing, analyzed by Microbiome Center…

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON53205

Source
ToetsingOnline

Brief title
SELECT-microbiota

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Bacterial infectious disorders
- Gastrointestinal therapeutic procedures

Synonym
Perioperative microbiota

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Gasthuis
Source(s) of monetary or material Support: Wetenschapsfonds Spaarne Gasthuis

Intervention

Keyword: 16S-analysis, Antibiotics, Colorectal, Microbiota

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the differences in microbiome composition and diversity between different microbiota samples. To achieve this objective, we will employ various statistical tests, including t-tests or ANOVA, to compare the alpha and beta diversity measures between microbiota samples.

Secondary outcome

1. Comparison of peri-operative changes in microbiota composition between colon cancer patients receiving preoperative oral antibiotic prophylaxis with or without amphotericin B.

2. Correlation between the gut microbiota composition and specific microbiota on site of an occurring post-operative infection.

3. Comparison of rectal and anastomotic microbiota composition for right and left sided colon resections

Study description

Background summary

Surgery remains the cornerstone in the curative treatment for colorectal

cancer. Despite the introduction of improvements in perioperative care, infectious complications after surgery remain a burden for patients and health-care expenses. Several recent randomized controlled trials show that oral antibiotic prophylaxis is associated with a reduction of postoperative infectious complications and potentially anastomotic leaks [1-4]. The SELECT-trial showed that patients who received oral antibiotic prophylaxis in the form of SDD had a significant reduction of preoperative Proteobacteria levels in their gut microbiota [1]. Subsequently, we also presented data which show that decreased levels of Proteobacteria were associated with a reduction in infectious complications [5]. Although this explicit evidence for a decrease in post-operative infectious complications, data on correlation between oral antibiotic prophylaxis like SDD and its effect on microbiota in the perioperative phase is scarce. Therefore, several important questions remain to be answered. First, it is currently unknown how the patient*s microbiota composition changes and repopulates in the perioperative phase and whether this can be predicted based on the original microbiota in patients using oral antibiotic prophylaxis as well as in control patients that not received oral antibiotics. Secondly, it is uncertain if swabs of the rectal microbiota are representative for the microbiota located at the site of the anastomosis (i.e. right sided colon or sigmoid). Thirdly, it is still unclear whether specific bacterial species can be identified as the cause of infectious complications, as suggested in our previous study [6]. The latter two questions are important as it has been proposed in animal studies that the presence of certain bacteria at the anastomotic site may cause or increase the risk of anastomotic leakage [7]. Fourthly, it is unknown what effect antifungal medication such as amphotericin B in SDD has on the perioperative microbiota composition. In addition, this study will provide knowledge on the prognostic value of a rectal swab for possible anastomotic complications.

Study objective

Primary Objective: Exploring peri-operative changes in microbiota composition between patient receiving oral antibiotics, oral antibiotics with amphotericin B or no oral prophylaxis, performed by 16S rRNA sequencing, analyzed by Microbiome Center Amsterdam (MiCA).
Secondary Objective(s):
1. Comparison of peri-operative changes in microbiota composition between colon cancer patients receiving preoperative oral antibiotic prophylaxis with or without amphotericin B.
2. Correlation between the gut microbiota composition and specific microbiota on site of an occurring post-operative infection.
3. Comparison of rectal and anastomotic microbiota composition for right and left sided colon resections

Study design

Prospective multicenter observational cohort study including a total of 120 patients, for each patient 5 swabs are taken on 4 time points, see figures 1 and 2. Follow-up is done in accordance with the Dutch guidelines on colorectal cancer. Duration of the study is 12 months, excluding follow-up.

Study burden and risks

Patients will undergo multiple peri-operative rectal swabs as well as an intra-operative swab from proximal and distal anastomotic and tumour sites. No negative side effects are anticipated besides minor discomfort of a rectal swab on the outpatient clinic.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients 18 years and older
Dutch or English speaking
Candidate for elective laparoscopic/open colorectal surgery with a primary anastomosis
Undergoing a right hemicolectomy, sigmoid resection or laparoscopic low anterior resection (LAR)
Biopsy-proven colorectal carcinoma (or a high index of suspicion of carcinoma on biopsy) with no imaging signs of distant metastasis

Exclusion criteria

No primary anastomosis or deviating stoma
Recent abdominal surgery (<4 weeks) or recent (<3 months) oral antibiotic treatment
Pregnancy
Unable to give informed consent
History of inflammatory bowel disease
ASA grade IV or higher
Immune suppressing medication
Received neoadjuvant treatment with chemotherapy, radiotherapy or immunotherapy.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2023
Enrollment:	120

Type:	Anticipated

Ethics review

Approved WMO Date:	18-10-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL84298.018.23