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PROtective ileoStomy versus ProtectivE colostomy in anterior Rectal resectIon: study protocol for a multicenter, open-label, randomised conTrolled studY (PROSPERITY)

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ABSTRACT

Introduction Loop ileostomy and loop colostomy are both used to form a protective stoma after anterior resection. Evidence regarding which of these two procedures is superior is lacking. Furthermore, no studies comparing changes in the microbiome after loop ileostomy or loop colostomy exist.

Methods and analysis This multicentre, open-label, superiority, individually randomised controlled trial will include patients who undergo anterior rectal resection with primary anastomosis with a protective stoma. The exclusion criteria are patients who already have a stoma, technical inability to create either type of stoma, aged <18 years and inadequate cooperation. Patients scheduled for anterior rectal resection will be randomised intraoperatively in a 1:1 ratio to undergo either loop ileostomy or loop colostomy. The primary outcome is cumulative stoma-related adverse events within 60 days after primary surgery, measured using the Comprehensive Complication Index (CCI). Secondary outcomes include all postoperative complications (measured using the CCI), number of hospital-free days within 30 days after primary surgery, quality of life at 2 months (measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaires-Core 30 and Colorectal 29), complications within 30 days after stoma closure (measured using the CCI) and kidney function (measured using estimated glomerular filtration rate) at 1 year. Tertiary outcomes are survival, kidney function and number of stoma site hernias at 5 years. The sample size was calculated to detect a mean difference of five CCI points between groups, resulting in a final sample size of 350 patients. Microbiome samples will be collected from the faeces and mucous membrane from patients in Helsinki University Hospital.

Ethics and dissemination The Ethics Committee of Helsinki University Hospital approved the study (approval number 4579/2024). The findings will be disseminated in peer-reviewed academic journals.

Trial registration ClinicalTrials.gov, NCT06650085, registered on 20 August 2024. Protocol version: Version 3.0, dated 17 April 2025.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study uses a prospective, multicentre, individually randomised controlled trial design, ensuring high methodological rigour.
⇒ Intraoperative randomisation minimises selection bias and ensures both stoma types are technically feasible.
⇒ Primary and secondary outcomes are assessed using the validated Comprehensive Complication Index, enhancing reliability and comparability.
⇒ The open-label nature of the trial may introduce bias, though stoma-related adverse events were rigorously defined before study initiation, outcome and adjudication committee members are blinded to treatment allocation.
⇒ Microbiome analysis is limited to one participating centre, which may affect the generalisability of those specific findings.

INTRODUCTION

Anterior resection or abdominoperineal resection with total mesorectal excision are the two standard methods used to treat middle and low rectal cancer.[1] The sphincter-saving anterior resection is generally preferred when tumour margins and patient fitness allow, because it is associated with better quality of life after surgery than abdominoperineal resection, which results in a permanent stoma.[2] However, anterior resection carries the risk of anastomotic leakage, a complication associated with costly postoperative morbidities and a negative impact on long-term outcomes, including reduced overall survival.[3]

Several preventive methods have been introduced to mitigate the risk of anastomotic leakage following anterior resection for rectal cancer. Among others, these techniques

Table 1 Randomised controlled trials in which loop ileostomy and loop colostomy in patients undergoing anterior resection were compared

Author	Number	Primary outcome	Main findings	Conclusions
Williams *et al*[32]	47 (23 LI vs 24 LC)	Stoma-related morbidity	LI: 3 (18%) LC: 11 (58%)	Favoured: LI
Khoury *et al*[33]	61 (32 LI vs 29 LC)	Anastomotic leakage after primary surgery	LI: 2 (6%) LC: 6 (21%)	Favoured: LI
Gooszen *et al*[34]	76 (37 LI vs 39 LC)	Stoma-related morbidity	LI: 9 (24%) LC: 1 (3%)	Favoured: LC
Edwards *et al*[35]	70, (34 LI vs 36 LC)	Clinically relevant anastomotic leakage	LI: 2 (6%) LC: 1 (3%) More other stoma-related complications in the LC group	Favoured: LI
Law *et al*[36]	80 (42 LI vs 38 LC)	Ileus after primary surgery	LI: 6 (14%) LC: 1 (3%) 5 cases of postoperative ileus, 2 of intestinal obstruction before stoma closure	Favoured: LC

LC, loop colostomy; LI, loop ileostomy.

include preoperative mechanical bowel preparation, oral antibiotics, intraoperative testing of anastomotic integrity and perfusion, anastomotic buttressing, anastomotic reinforcement and creation of a protective stoma.[4]

Use of a protective stoma has been common practice in low anterior resection for decades.[5] Diverting faeces is thought to reduce intraluminal pressure and decrease the bacterial load at the distal anastomosis.[6] Although a protective stoma does not reduce the incidence of anastomotic leakage,[7 8] it does limit morbidity by lowering the risk of faecal peritonitis and septicaemia in the event of a leak.[9]

Loop ileostomy and loop colostomy are the two methods used to create a temporary protective stoma.[4] Despite their long-standing use, no clear superiority of one over the other has been established, resulting in a large variation in the stoma type used between surgeons, centres and countries.

We are aware of five randomised controlled trials in which the use of loop ileostomy and loop colostomy during anterior resection for rectal cancer has been compared (table 1). These trials took place more than two decades ago, used small sample sizes and had various outcomes. Several retrospective series have also compared the two stoma types, but these studies were limited and biased by diverse confounding factors. Meta-analyses, also including retrospective series, indicate differing risk-benefit profiles for the two types of stomata; loop ileostomy may result in fewer parastomal hernias, prolapses and stoma retractions, whereas loop colostomy appears to result in fewer problems related to dehydration.[10 11] Regarding stoma closure, loop ileostomy may be associated with a lower incidence of infection at the surgical site but a higher incidence of postoperative bowel obstruction.[10 11] Adding to this debate, one nationwide study reported an alarming rate of renal failure in patients with loop ileostomy,[12] and another recent study linked loop ileostomy with a high incidence of low anterior resection syndrome.[13]

In recent years, a relationship between pathological imbalance in the colonic microbiome and colorectal cancer has been discerned.[14] The colonic microbiome is known to play a role in carcinogenesis,[14 15] as well as progression[16 17] and treatment of colorectal cancer.[17 18] We are aware of only one study that compared the microbiomes of patients with colorectal cancer with or without loop ileostomy or colostomy; this recent observational cohort study conducted in Japan involved 165 patients.[19] In that study, patients with stoma had fewer microbes favourable for cancer immunotherapy than patients without. No studies comparing the differences in microbiomes between loop ileostomy and loop colostomy are available. Given that the colonic microbiome is recognised to play a significant role in treating colorectal cancer, important differences in the colonic microbiomes of patients undergoing loop ileostomy and loop colostomy may exist.[14–18]

To provide level 1 evidence for clinical practice, we designed the PROSPERITY trial (PROtective ileoStomy versus ProtectivE colostomy in anterior Rectal resectIon—a multicentre, open-label, randomised conTrolled studY). This trial primarily aims to compare loop ileostomy to loop colostomy in terms of stoma-related adverse events. The study also includes microbiological analyses to assess the changes in and role of the microbiome in patients undergoing either of the stomata. In this study, we hypothesised that protective loop colostomy will result in fewer and/or less severe stoma-related adverse events than a loop ileostomy within 60 days.

METHODS AND ANALYSIS

Study design

The PROSPERITY trial is a multicentre, open-label, superiority, individually randomised study. The trial will be coordinated by the Helsinki University Hospital, which will oversee study implementation and ensure adherence to the protocol. The steering committee, composed of adjunct professors from Helsinki University Hospital, will provide scientific guidance and strategic oversight throughout the trial. The outcome adjudication committee consists of three consultant gastroenterological surgeons who are not involved in patient recruitment, clinical care, data collection or data processing. All data presented to the outcome adjudication committee will be blinded for the allocation group by the data management team to ensure impartial assessment of the outcomes. The data management team will be responsible for collecting, processing and validating data to maintain the integrity and accuracy of the study findings. The participating hospitals include all the university hospitals in Finland, namely, Helsinki University Hospital, Turku University Hospital, Tampere University Hospital, Oulu University Hospital and Kuopio University Hospital. More hospitals may join the trial after its commencement. The study was registered with ClinicalTrials.gov (NCT06650085) prior to commencement, and the Ethical Committee of Helsinki University Hospital approved the study design (approval number 4579/2024). This protocol is reported according to the guidelines of the Standard Protocol Items: Recommendations for Interventional Trials statement.

Inclusion criteria

Patients undergoing elective anterior resection—resection of the rectum with colorectal or coloanal anastomosis—due to rectal neoplasia, with a protective stoma planned, will be assessed for eligibility.

Exclusion criteria

The exclusion criteria are: (1) the patient already has a stoma or an additional stoma is created during surgery; (2) technical inability to perform ileostomy or colostomy, for example, previous bowel resection or anatomical factors; (3) aged <18 years; and (4) inability of the patient to adequately cooperate.

Trial intervention

The intervention groups will be the (1) loop colostomy and (2) loop ileostomy groups. Both types of protective stomata will be created using standard surgical techniques; stoma sites, both for ileostomy (typically lower right quadrant) and colostomy (typically upper right quadrant, right transversostomy) are marked preoperatively, with the patient in a sitting position. A circular or transverse incision is made into the surface of the skin at the place thus marked. The subcutaneous tissue is dissected in a cylindrical shape. A cross-shaped or horizontal incision is made in the external fascia of the rectus sheath. The rectus muscle is separated, not transected, to reach the internal fascia of the rectus sheath; a cross-shaped or horizontal incision, the approximate length of two finger widths, is made in the sheath. A loop of the transverse colon and/or ileum is brought to the surface of the skin with two lumens draining into a stoma pouch. The transverse colon and/or ileum is attached to the skin using absorbable sutures, preferably with three-point sutures. A stoma bridge can be used if warranted. The stoma incision should not be made outside the rectal sheath, and the distance from the costal margin should be sufficient to allow for proper fixation of the stoma pouch. All surgeries should be performed by a consultant colorectal surgeon or by a surgeon under the direct supervision of a consultant colorectal surgeon, who has experience in performing both types of stoma surgeries. All participating hospitals follow Enhanced Recovery After Surgery principles, although the specific protocols may vary slightly between centres.

Randomisation

Recruitment will take place before surgery, preferably at the preoperative clinical visit. The patient will need to provide written informed consent before enrolment to the trial. The final inclusion and randomisation will occur during surgery, after the anterior resection and colorectal or coloanal anastomosis have been completed and the surgeon has confirmed that a protective stoma is required and that both ileostomy and colostomy are technically feasible.

Patients will be individually randomised in a 1:1 ratio to undergo either loop ileostomy or loop colostomy. The randomisation sequence will be generated by computer using a variable block size of 4–6. The randomisation sequence will be stratified according to: (1) centre, (2) body mass index (<30 kg/m^2 and ≥30 kg/m^2) and (3) any neoadjuvant treatment administered (yes/no; radiotherapy, chemotherapy or a combination of the two). Allocation will be performed using the Research Electronic Data Capture (REDCap) software.

Blinding

The study will be conducted as an open-label trial because the blinding of patients, treating personnel or data collectors is not considered feasible. However, to minimise bias in the open-label design, the primary outcome has been carefully designed to be as objective as possible. Furthermore, outcomes that are not predefined will be assessed by a committee blinded to the study group.

Study outcomes

The primary outcome is the occurrence of prespecified stoma-related adverse events within 60 days from primary surgery, reported using the Comprehensive Complication Index (CCI). What constitutes a stoma-related adverse event can be subjective; therefore, these events have been predefined and are listed in box 1. Similarly, adverse events that are not considered stoma-related are detailed in box 2. The list of stoma-related adverse

Box 1 Stoma-related adverse events

Complication

Stoma necrosis*†
Stoma prolapse*†
Parastomal hernia*†
Bleeding from stoma site*†
Stoma retraction or lift of the stoma from the surface of the skin*†
Peristomal skin irritation requiring a change in treatment (additional changes of the stoma bag, use of topical creams, etc)*†
Stoma stenosis or obstruction*†
Peristomal fistula or abscess*†
Mucosal hypertrophy of the stoma requiring a change in treatment
Ileus, included if occlusion related to the stoma site is present, but excluded if a specific other reason for ileus is identified (eg, internal hernia unrelated to stoma or mechanical bowel obstruction not at the site of stoma)
Pneumonia, if caused by aspiration due to ileus (ileus, as described above)
Surgical site infection at stoma or another incision site
Fascial dehiscence, if occurring with surgical site infection or ileus (ileus, as described above)
Electrolyte imbalance or acute kidney failure (kidney disease: improving global outcomes stage 1 (increase in serum creatinine of >1.5 µmol/L × baseline or >26.5 µmol/L or more or requirement for intravenous fluids due to high stoma output (>1500 mL/day); each day on which intravenous fluids are required is counted as one complication.
Cerebrovascular, cardiovascular or thromboembolic event, if occurring at a time of dehydration and high-output stoma (>1500 mL/day)
Atrial fibrillation or other arrhythmia, if occurring with dehydration or electrolyte imbalance and high-output stoma (>1500 mL/day)

*Clavien-Dindo class 1 if no intervention is required, otherwise according to intervention based on Clavien-Dindo classification.
†Counted once for first occurrence; subsequently, only an additional visit(s) to the medical unit (including stoma nurse, emergency department or other) for the same reason is counted as another cumulative adverse event.

Box 2 Adverse events that are not considered Stoma-related

Complication

Pneumonia, if not caused by aspiration due to ileus
Urinary tract infection
Cerebrovascular, cardiovascular or thromboembolic event, if occurring without dehydration
Bleeding, other than at the stoma site
Delirium, if occurring without dehydration or electrolyte imbalance
Urinary retention
Peripheral nerve paresthesia and or paralysis
Fever, unknown origin
Clostridium difficile infection
Respiratory distress
Cholecystitis
Atrial fibrillation or other arrhythmia, if occurring without dehydration or electrolyte imbalance
Ascites
Epidural complications (headache, haematoma, etc.)
Fascial dehiscence, if occurring without surgical site infection and without ileus
Intestinal perforation, if not anastomotic leakage and not at the stoma site
Haematuria
Allergic reactions
Abnormal pain
Anastomosis stricture
Pleural effusion
Ureteral complications (stone, stricture, lesion, etc)
Bowel obstruction, if the mechanical obstruction is not caused by the stoma site
Bowel necrosis, not at the stoma site
Anastomotic leakage
Intra-abdominal abscess, not located at the stoma site
Acute kidney injury without concomitant high-output stoma (>1500 mL/day)

events was compiled based on a comprehensive literature search conducted using the terms, *ileostomy and colostomy and complications* from 2022 to 2023. In total, 99 publications were assessed, and all relevant complications were included in the list. From this list, a panel of 10 consultant surgeons assessed if an adverse event was stoma-related or not. A second round of assessment was performed for those adverse events that did not achieve 90% agreement. Any other adverse event that occurs within 60 days from primary surgery and is not included in the list will be reviewed by the outcome adjudication committee. The committee members will be blinded to the allocation group. The time frame of 60 days was chosen in consideration of the recommendation that protective stomata be closed within 2–3 months of the primary surgery. Should a stoma be reversed within 60 days, data regarding the adverse events will be collected up to the point of reversal surgery. The CCI is based on the Clavien-Dindo classification and takes into account the cumulative burden of adverse events.[20] Index values can range from 0 to 100, with a value of 0 indicating no events and one of 100 indicating death due to an adverse event. Details of types of adverse events will be reported, but not statistically analysed.

The secondary outcomes include: (1) all complications within 30 days from primary surgery, reported using the CCI to capture all—not only stoma-related—postoperative complications; (2) all complications within 30 days from stoma closure, reported using the CCI and including only patients who have undergone stoma closure within 1 year from primary surgery; (3) number of hospital-free days within 30 days from the primary surgery; (4) quality of life at 2 months from primary surgery, measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaires-Core 30 and Colorectal 29 (QLQ-C30+QLQ-CR29). A 2-month period was chosen as the time point to reflect quality of life while the stoma is still in place, but with enough time having passed to recover from the primary surgery; and (5) change in kidney function at 1 year, compared with initial kidney function, measured using the difference in estimated glomerular filtration rate (eGFR) before and 1 year after primary surgery. Tertiary outcomes include:

(1) 5-year overall survival; (2) 5-year disease-free survival, including only patients with M0 at primary surgery undergoing radical R0/1 surgery; (3) change in kidney function at 5 years, compared with initial kidney function, that is, difference in eGFR before and 5 years after primary surgery; (4) number of incision hernias at the ostomy site within 5 years from the primary surgery. Only patients who have undergone successful stoma closure and are alive at 5 years will be included in this analysis; (5) cumulative death-censored successful stoma closure, within 5 years from primary surgery. If a stoma closure is attempted but, for example, an anastomotic dehiscence occurs and the stoma is modified, it will not be considered a successful stoma closure; and (6) quality of life at 5 years, measured using the European Quality of Life 5 Dimensions 5 Level Version (EQ-5D-5L), QLQ-C30, QLQ-CR29, and—only for patients without stoma—low anterior resection syndrome scores (LARSs). The exploratory outcomes/variables are: (1) quality of life within 1 year (EQ-5D-5L at 2 months, 6 months and 1 year after primary surgery, LARS at 6 months and 1 year after primary surgery (only for patients without a stoma) and QLQ-C30, QLQ-CR29 at 6 months and 1 year after primary surgery), (2) total number of anastomotic leakages reported with grading[21] within 60 days of primary surgery and (3) intestinal microbiome composition and functional potential (only for patients at Helsinki University Hospital) during the stoma phase and stabilisation of the microbiome after stoma closure. We will correlate bacterial taxa with the clinical outcomes to study whether microbiome characteristics are linked to clinical outcomes in the short term (1 year) or long term (5 years).

Follow-up

CT imaging with per rectal contrast medium, colonography or endoscopy will be used to assess colorectal and/or coloanal anastomosis at approximately 6 weeks after primary surgery. At this time, contact will be made either through an outpatient visit or by telephone. Patients will also be telephonically monitored every 2 weeks by the study nurse to identify any potential postoperative or stoma-related adverse events for up to 60 days after primary surgery. A follow-up call will be made 30 days after the surgery to close the stoma. If, via a telephone call, suspicion of a complication is raised or the patient reports a complication, patients will be requested to undergo a physical assessment as necessary. Patients will be contacted by letter or telephone at 1 year and 5 years after primary surgery. Creatinine tests will be conducted at 1 year and 5 years after primary surgery to calculate eGFR. Outcomes will also be assessed from patient records and, if necessary, by requesting patient records from other hospitals. Patients will be asked to complete the EQ-5D-5L,[22] QLQ-C30,[23] QLQ-CR29[24] and LARS[25] assessments before and at 2 months, 1 year and 5 years after primary surgery. If necessary, the patient can be contacted by letter or telephone at any time.

Costs and funding

The hospitals involved in this study will not carry any additional costs concerning the surgical treatment administered to patients. This is because both interventions included in this study are standard procedures used daily in clinical practice when treating patients with rectal tumours. Patients will not require additional visits or examinations due to their participation in the study. Follow-up will be conducted via telephone by a study nurse. Routine follow-up according to normal clinical practice after rectal surgery is up to 5 years and includes the necessary laboratory tests. The cost of handling and analysing microbiome samples, and researcher and study nurse salaries will be paid from research grants. This is an investigator-initiated study without any commercial funders.

Intestinal microbiome analysis

Samples will be obtained from faeces stored in the colon and the mucous membrane biopsies of all patients undergoing preoperative endoscopy at Helsinki University Hospital. Mucous membrane biopsies will be obtained at the planning visit, during the primary surgery, at the stoma closure and at the 1-year follow-up visit. Stool samples will be collected preoperatively, during the primary surgery and during the stoma closure, from the stoma pouch (table 2). Additional samples will be taken at 3 months, 6 months and 12 months after stoma closure. Microbial swab samples will be taken from the rectum during stoma closure. Samples will be used to analyse the microbiome and mucosal gene expression. Mucosal samples will be directly stored in RNAlater solution for analysis, and faecal samples will be frozen and stored at −80°C within 1 day of defecation.

The primary method of analysis for mucosal samples will be high-throughput sequencing of the 16S ribosomal RNA (rRNA) genes of bacteria. Profiling of 16S rRNA genes reveals the composition of the bacterial population. The primary method of analysis of faecal samples will be shotgun metagenomic sequencing, in which the genetic material of the microbes is extensively sequenced, enabling the functional potential of the microbiome, in addition to its composition, to be studied. The analyses will be performed using methods and bioinformatic pipelines that are routinely used and frequently updated within the research group. The research group has extensive experience studying the composition of the intestinal microbiome, therapeutic use of intestinal bacteria (faecal transplants) and host-microbe interactions.[26–29]

Sample size

For power calculation purposes, a sample of 95 consecutive patients who underwent anterior resection with loop colostomy for rectal cancer at Helsinki University Hospital for the previous trial[30] were assessed. The mean and SD of stoma-related CCI values in this group were 2.5 and 6.2 points, respectively. The sample size

Table 2 Participant timeline

	Enrolment	Primary surgery	Follow-up, 60 days after primary surgery, phone call	Follow-up, 6 months after primary surgery, phone call/letter	Follow-up, 1 year after primary surgery, phone call/ letter	Stoma closure	Follow-up, 30 days after stoma closure, phone call	Follow-up, 5 years after primary surgery, phone call/ letter
CRF	CRF1	CRF2–3	CRF4	CRF5	CRF6	CRF8	CRF9	CRF7
Written informed consent	X							
Inclusion/ exclusion evaluation	X	x						
Randomisation		x						
QOL	X		x	x	x			x
Medical history	X					x		
eGFR and creatinine	X	x	x		x	x		x
Operative details	X	x				x		
Assessment for adverse events/ complications		x	x				x	
Assessment for stoma site hernia								x
Assessment for recurrence					x			x
Assessment for survival					x			x
Microbiome samples	MMB, SS	MMB, SS			MMB, SS	MMB, SS, S		

CRF, case report form; eGFR, estimated glomerular filtration rate; MMB, mucous membrane biopsy; QOL, quality of life; S, swab sample from rectum; SS, stool sample.

calculation was based on detecting a 5-point difference in the CCI mean values between the groups, hypothesising 2.5 points in the loop colostomy group and 7.5 points in the loop ileostomy group, with an SD of 14. A 10-point difference in the CCI mean values reflects a single grade difference in the established Clavien-Dindo classification,[20] and stoma-related adverse events are usually minor; therefore, we considered a 5-point difference would indicate a clinically meaningful threshold. With a power of 90% and significance level set at 5%, 330 patients are required.[31] Taking into account a loss to follow-up of up to 5%, the final sample size required was calculated to be 350 patients.

Statistical analysis plan

Primary analyses will be conducted on an intention-to-treat basis. The primary outcome will be analysed using either the Mann-Whitney U test or t-test, bootstrapped or log-transformed if necessary. Secondary outcomes will be analysed using either the Mann-Whitney U test or t-test for continuous variables, depending on the distribution and the χ^2 or Fisher's exact test for categorical variables. If necessary, log transformation or a bootstrapped t-test will be performed on non-normally distributed continuous variables. Tertiary outcomes will be analysed separately when a minimum of the 5-year follow-up data for all patients are available. Survival analysis will be conducted using the Kaplan-Meier method and log rank test; the eGFR will be analysed using the Mann-Whitney U test or t-test. The Kaplan-Meier method and log-rank test will be used to estimate the cumulative incidence of incisional site hernias. Statistical significance will be set at a two-tailed p value of <0.05. Effect sizes will be reported using relative risk, corrected from the ORs with 95% CIs or as Wilcoxon effect sizes ($r=z\sqrt{n}$).

Prespecified subgroup analyses according to: (1) body mass index (<30 kg/m^2 and >30 kg/m^2), (2) surgical approach (minimally invasive vs open surgery), (3) neoadjuvant treatment (yes/no), (4) adjuvant treatment (yes/no) and (5) cancer stage (stages 1–3 vs stage 4) will be conducted.

Conducting interim analyses is not planned as both arms are currently standard care and considered safe.

Data collection and management and post-trial care

Data will be collected using Case Report Forms 1–8 within the REDCap web application (table 2). Data will be monitored by the Clinical Research Institute Helsinki University Hospital monitoring services for researcher-initiated clinical studies or similar services for the other university hospitals. Monitoring will be performed in accordance with currently valid official rules and regulations and the Good Clinical Practice guidelines. Access to data will be restricted to monitors, investigators and study nurses. Post-trial care is not warranted since the interventions used in this trial are standard, widely accepted treatments for rectal cancer and patients will receive standard clinical care outside of the trial.

Schedule

The research project is scheduled to begin during 2024 or once the study protocol has been peer reviewed and potentially updated. Patient recruitment is estimated to take approximately 2–3 years to reach the sample size determined by the power calculation. The follow-up phase is estimated to continue until the end of 2032, 5 years from the time the last patient undergoes primary surgery.

Patient and public involvement

Two patients who underwent anterior resection with a protective colostomy as well as a stoma nurse contributed to developing the study design and consent forms. The patients wished to remain anonymous.

ETHICS AND DISSEMINATION

The study plan has been approved by the Ethics Committee of Helsinki University Hospital (approval number 4579/2024). Permission to conduct the study will be sought from each participating centres' institutional review board. All patients meeting the inclusion and/or exclusion criteria are eligible to participate in the trial, regardless of their gender, sex or race. All patients in the study will be adults and must have sufficient comprehension of the Finnish, Swedish or English language and information provided in the written informed consent form (online supplemental material). The recruiting surgeon will inform each patient in verbal and written form. Participation in the study will be voluntary and will not affect the patient's other treatment. The informed consent form must be signed by the patient and the recruiting surgeon before inclusion in the study. Patients may withdraw their consent at any time without losing any of their rights as a patient.

Both intervention arms (loop ileostomy and loop colostomy) are standard treatments and the choice between them is based on surgeon or centre preference outside the trial. Thus, randomising patients to either intervention is considered ethical.

During the study, patient identification data will be collected in a study folder. The data collected during the study will be stored and analysed without the patient identification data. At randomisation, each study patient will receive a study number, which will be linked to their identification information in the study folder. Data will be stored in a locked room and electronic data will be stored on password-protected drives of hospital computers. Data will be processed in accordance with the General Data Protection Regulation and data processing will be conducted based on Article 6 (e) in conjunction with Article 9 (i) of the regulations.

The results will be reported in a scientific paper submitted to an international peer-reviewed journal. The first report will cover primary, secondary and exploratory outcomes up to the 1-year follow-up examination. The second report will address outcomes up to 5 years. Microbiological analyses will be reported separately once 1-year and 5-year outcomes are available. All reports will be published with open access, provided the journal has an open access option and funding for article processing charges is obtained. The use of professional writers is not intended.

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