

Improving consumption compliance and satisfaction with quality coffee to enhance bowel recovery after colorectal surgery

Submission date 07/05/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/05/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/11/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Colorectal surgery is frequently followed by a prolonged absence of bowel function called post-operative ileus (POI). Recent studies have shown that coffee consumption after surgery leads to a faster recovery of bowel function. However, such a protocol with coffee served at the hospital is not always the most pleasant experience and compliance is unknown. This study looks at issues that are key to ensuring widespread implementation and routine use of a standardized coffee for POI prevention, such as choosing a freshly made quality coffee “at the patient’s bedside”, according to personal preference (flavour and amount). This study aims to measure patients’ compliance and satisfaction with tasty, freshly made and high-quality coffee made using a capsule system to enhance compliance for POI prevention after colorectal surgery.

Who can participate?

Patients aged 18 years old and over who are scheduled for elective colorectal surgery or stony closure in our hospital

What does the study involve?

The study involves drinking 3 coffees per day. The participant can choose among a selection of 4 different types of coffee ensuring a variety of flavours to satisfy different tastes and add a ludic dimension. The participant is asked to complete a diary about consumption and satisfaction with the experiment.

What are the possible benefits and risks of participating?

The participant will benefit from the effect and the satisfaction of freshly brewed coffee, with no specific risk.

Where is the study run from?

January 2021 to October 2022

When is the study starting and how long is it expected to run for?
The visceral surgery service at Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne, Switzerland

Who is funding the study?
Nestlé Health Science

Who is the main contact?
Constant Delabays, constant.delabays@chuv.ch

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Improving compliance and satisfaction with quality coffee in-take to enhance bowel recovery after colorectal surgery

Acronym

Coffee trial

Study objectives

The key to ensure widespread implementation and routine use of a standardized coffee for post operative ileus prevention is to choose a freshly made quality coffee “at the patient’s bedside”, according to personal preference (flavour and amount).

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 07/09/2021, CER VD (Avenue de Chailly 23, Lausanne, 1012, Switzerland; +41 21 316 18 30; secretariat.CER@vd.ch), ref: CER-VD 2021-01430

Study design

Prospective monocentric single-arm feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Compliance to coffee in the post operative setting after elective colorectal surgery or ostomy closure

Interventions

Daily doses of freshly made coffee with a capsule coffee system will be proposed and served to participants 3 times a day, starting from the first day after surgery, for a total of 3 days. This protocol and schedule are based on studies demonstrating the effectiveness of coffee intake in POI prevention. Doses are scheduled on a standard basis (8:00 a.m., 12:00 p.m. and 3:00 p.m.) but remain flexible and can be adapted according to the wishes of each patient. Participants will also be able to use the coffee machine themselves, thus stimulating early mobilization. A selection of different types of coffee is also proposed, ensuring a variety of flavours to satisfy every participant's taste and add a ludic dimension. In addition, the coffee will be offered in two ways: Espresso (40 ml) or Lungo (110 ml), at the patient's discretion. The dose of caffeine is standardized and equal in each capsule, varying between 60 and 80 mg depending on the type and variety of coffee. Finally, to guarantee an optimal sensory and visual experience, the coffee will be offered in glass cups. The day before surgery, participants will receive a diary to self-assess postoperative compliance to the suggested schedule, resp. its reasons and reasons for non-compliance. After every coffee proposal, compliance and/or reason for non-compliance will be reported by the patient and controlled by nurses. At the end of the 9 doses planned by the study, a survey will be conducted to evaluate the experience and satisfaction of each participant (patient-related experience measure PREM). Secondary outcomes such as time to first transit, complication and length of hospital stay are systematically assessed in a prospective enhanced recovery (ERAS) database and will be extracted for this study. Post-operative surveillance and care will not deviate from the standard protocol for colorectal procedures in the Department of Visceral Surgery. These consist of standardized postoperative controls (dedicated care maps and clinical itineraries). There is no exclusion criterion for patients after enrolment. No material will be sampled for this study and no particular biases are expected.

Intervention Type

Supplement

Primary outcome measure

1. Compliance with coffee measured using a capsule system at the suggested schedule using a self-report diary during the three first postoperative days (ie a total of 9 possible coffees)
2. Reason for non-compliance to coffee measured using a self-report diary during the first three days

Secondary outcome measures

1. Satisfaction and the experience felt by each participant measured using a specific and dedicated Patient-Related Experience Measure (PREM) questionnaire after 3 postoperative days
2. Bowel recovery (time to first flatus and first bowel movement), measured using data documented by a nurse during hospitalisation
3. Length of hospital stay (interval from the day of operation until the day of discharge) measured using medical records at the end of the study
4. Post-operative 30-day complication measured using the Dindo-Clavien classification during hospitalisation and 30 days follow-up

Overall study start date

15/01/2021

Completion date

31/10/2022

Eligibility

Key inclusion criteria

Scheduled for elective colorectal surgery or stony closure in our hospital

Participant type(s)

Patient

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

50

Total final enrolment

53

Key exclusion criteria

1. Impaired cognitive status
2. Intolerance to coffee
3. Pregnancy
4. Pre-existing ileus
5. Need for post-operative surveillance in intensive or intermediate care units

Date of first enrolment

01/11/2021

Date of final enrolment

31/08/2022

Locations

Countries of recruitment

Switzerland

Study participating centre

Centre Hospitalier Universitaire Vaudois

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Sponsor information

Organisation

University Hospital of Lausanne

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Sponsor type

Hospital/treatment centre

Website

<https://www.chuv.ch/fr/chuv-home/>

ROR

<https://ror.org/05a353079>

Funder(s)

Funder type

Industry

Funder Name

Nestlé Health Science

Alternative Name(s)

Nestlé Health Science S.A.

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/06/2024

Individual participant data (IPD) sharing plan

The Datasets generated during and/or analyses during the current study will be available upon request from Constant Delabays, constant.delabays@chuv.ch

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			28/11/2024	No	No