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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

Registration date
08/05/2024

Overall study status
Completed

Last Edited
28/11/2024

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Type(s)
Public, Scientific

Contact name
Dr Constant Delabays

ORCID ID
https://orcid.org/0000-0002-9346-9486

Contact details
Rue du Bugnon 46
Lausanne
Switzerland
1011
+41799546922
constant.delabays@chuv.ch

Type(s)
Principal investigator

Contact name
Prof Martin Hübner

ORCID ID
https://orcid.org/0000-0002-4521-8279

Contact details
Rue du Bugnon 46
Lausanne
Switzerland
1011
+41 079 556 15 06
Martin.Hubner@chuv.ch

Type(s)
Public

Contact name

Dr Constant Delabays

Contact details
Rue du Bugnon 46
Lausanne
Switzerland
1011
+41799546922
delabays.constant@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
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

Completion date
31/10/2022

Eligibility

Key inclusion criteria
Scheduled for elective colorectal surgery or stony closure in our hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

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
Rue du Bugnon 21
Lausanne

Switzerland
1011

Sponsor information

Organisation
University Hospital of Lausanne

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

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