

Comparison of frailty screening instruments in terms of their ability to predict outcomes of colorectal surgery in older adults

Submission date 03/07/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aging of society leads to increasing demand for colorectal surgical procedures in older patients. Frail older patients with a high risk of experiencing adverse outcomes after surgery should be identified before surgery in order to determine who would benefit most from additional geriatric care and follow-up. Many frailty screening instruments have been developed, but due to a lack of comparative studies, there is still no consensus as to which screening instrument would be most appropriate for the preoperative practice in elective colorectal surgery.

This study will be performed as part of a quality improvement project in the UH Leuven, in which a surgical-geriatric co-management program will be developed and implemented in the abdominal surgery department. The aim of this study is to investigate which frailty screening instrument would be best suited to select patients for the co-management program.

Who can participate?

Patients planned for elective colorectal resection for cancer or benign disease in an enhanced recovery after surgery pathway, aged 70 and over on the day of surgery

What does the study involve?

At the preoperative consultation (approximately 1 month before surgery), after agreement to participate, three short functional tests will be performed: handgrip strength, mini-cog test, timed-up-and-go test. This will take about 5 minutes. The patients will also receive a questionnaire to complete with the research assistant or at home. Completion of the questionnaire will take about 15 minutes. Further information will be collected by consulting the electronic medical record and, if necessary, the treating physician or nurse. Outcome data will be collected at 1 week and 1, 3 and 6 months after the surgery.

What are the possible benefits and risks of participating?

Participants will not receive any compensation for participation in this study. The study will lead to better knowledge about frailty screening and postoperative outcomes in relation to frailty in older patients undergoing elective colorectal resections. There is a small chance that

participants will lose their balance when performing the timed-up-and-go test. However, this test will always be conducted under the supervision of a person with a background in healthcare. Possible risks are covered by an insurance policy.

Where is the study run from?

University Hospital of Leuven (Belgium)

When is the study starting and how long is it expected to run for?

July 2020 to December 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Katleen Fagard

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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Version 3, 12-06-2020

Study information

Scientific Title

Comparison of preoperative frailty screening instruments in older adults undergoing elective colorectal surgery: a prospective observational study

Acronym

G-ERAS frailty study

Study objectives

The aim of this study is to compare the diagnostic characteristics of frailty screening instruments to identify a target group that will benefit most from geriatric-surgical co-management to avoid adverse postoperative outcomes, such as postoperative complications, prolonged length of stay, functional decline and higher level of care needs.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 24/06/2020, Ethics Committee Research UZ / KU Leuven (EC Research, Herestraat 49, 3000 Leuven, Belgium; +32 (0)16 34 86 00; ec@uzleuven.be), ref: S 63864

Study design

Prospective single-centre observational cohort study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Frailty in older adults undergoing elective colorectal resections

Interventions

At the preoperative consultation (approximately 1 month before surgery), after agreement to participate, three short functional tests will be performed: hand grip strength, mini-cog test, timed-up-and-go test. This will take approximately 5 minutes. The patients will also receive a questionnaire to complete with the research assistant or at home. Completion of the questionnaire will take approximately 15 minutes. Further information will be collected by consulting the electronic medical record and, if necessary, the treating physician or nurse.

Outcome data will be collected at 1 week and 1, 3 and 6 months after the surgery.

Intervention Type

Other

Primary outcome(s)

The severity of in-hospital postoperative complications according to the Clavien-Dindo classification, assessed at discharge

Key secondary outcome(s)

1. Prolonged postoperative length of stay (LOS), defined as LOS > 75th percentile, assessed at discharge
2. Functional decline in basic activities of daily living (bADL), defined as the difference in bADL score compared to the preoperative score at 1 week and at 1, 3, 6 months after surgery
3. Functional decline in instrumental activities of daily living (iADL), defined as the difference in iADL score compared to the preoperative score at 1 week (if discharged) and at 1, 3, 6 months after surgery
4. Discharge to an increased level of care compared to the preoperative residence, assessed at discharge: levels of care in increasing order are:
 - 4.1. Place of residence with same assistance compared to the preoperative situation
 - 4.2. Place of residence with increased assistance compared to the preoperative situation
 - 4.3. Rehabilitation/Convalescence stay
 - 4.4. Nursing home admission

Completion date

23/12/2022

Eligibility

Key inclusion criteria

1. Aged 70 and over on the day of the surgery
2. Elective colorectal resection for cancer or benign disease
3. Enhanced recovery after surgery pathway

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

172

Key exclusion criteria

1. Patients lacking decision-making capacity
2. Patients undergoing emergency surgery, reoperations for surgical complications, hyperthermic intraperitoneal chemotherapy, stoma closure or transit repair, rectopexy or prolapse surgery, trans-anal procedures, proctological operations or local stoma procedures
3. Patients whose surgery was omitted
4. Patients who are unable to understand and speak Dutch

Date of first enrolment

08/07/2020

Date of final enrolment

08/07/2022

Locations**Countries of recruitment**

Belgium

Study participating centre

University Hospital of Leuven (UH Leuven)

Geriatrics Department University Hospitals Leuven, Herestraat 49

Leuven

Belgium

3000

Sponsor information**Organisation**

Universitaire Ziekenhuizen Leuven

ROR

<https://ror.org/0424bsv16>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

Anonymized study data will be available on request. Data will be collected using REDCap®, an electronic case report form (eCRF) that entails a possibility to export data into an Excel file. Colleague researchers can request all necessary data, e.g for meta-analysis, which we will send in an anonymized Excel file. Data can be requested by contacting Dr Katleen Fagard (by mail) after publication of the study in a peer-reviewed journal. The patients will have signed an informed consent form (in Dutch) in which they agree to use the collected data for scientific research and for publication, provided that the Belgian and European law concerning privacy protection is respected. This means that only anonymized data will be shared.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Participant information sheet	29/12/2024	21/01/2025	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	Study website	12/06/2020	07/08/2020	No	No
Study website		11/11/2025	11/11/2025	No	Yes