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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

Registration date
02/08/2020

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Study website
https://gbiomed.kuleuven.be/english/research/50000687/50000630/researchprojects/geras

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
06/07/2020

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

Age group
Senior

Sex
Both

Target number of participants
135

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

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Sponsor information

Organisation
Universitaire Ziekenhuizen Leuven

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Sponsor type
Hospital/treatment centre

Website
https://www.uzleuven.be/nl/geriatrie

ROR
https://ror.org/0424bsv16

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of the study will be submitted by the core research team as conference abstracts and as publications in professional journals and international peer-reviewed journals. Before the start of the study, a publication policy will be distributed for approval.

Intention to publish date

31/07/2024

Individual participant data (IPD) sharing plan

Anonymized study data will be available on request. Data will be collected using REDCap®, an electronic case report from (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?
Protocol file		12/06/2020	07/08/2020	No	No
Results article		29/12/2024	21/01/2025	Yes	No