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Study on frail patients undergoing elective and emergency cholecystectomy

Submission date	Recruitment status	[_] Prospectively registered
30/06/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/11/2020	Digestive System	

Plain English summary of protocol

Background and study aims
The gallbladder is a small, pouch-like organ found underneath the liver, which is responsible for storing bile (a chemical produced by the liver which helps with the digestion of fats) and making it more concentrated. In some cases, if there is too much cholesterol in the bile inside gallbladder, it can lead to the development of small stones (gallstones). In some cases gallstones can be very painful and it may be necessary for the gallbladder to be surgically removed. Older patients experience more complications after gallbladder removal compared with younger patients. However, most studies have not considered patient frailty, particularly in patients who undergo emergency gallbladder removal. The aim of this study is to find out whether there is a link between frailty and poor surgical outcomes (complications and death).

Who can participate?
Patients aged 65 and over who have gallstones who are scheduled for a routine or emergency gallbladder removal.

What does the study involve?
All patients are assessed using the Geriatric Assessment (GA) on the day that they are admitted to hospital. This includes a range of questionnaires and tests designed to evaluate the patient's physical and emotional functionality as well as their nutritional status and the medications they take, so that their frailty can be determined. Participants then undergo their surgery as per standard practice and are followed up for thirty days so that any complications or death after surgery can be recorded, as well as the length of their hospital stay. This information is then compared with the results of the GA in order to look at the link between frailty and surgical outcomes.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
3rd Department of General Surgery, Jagiellonian University Medical College (Poland)

When is the study starting and how long is it expected to run for?
January 2013 to March 2015

Who is funding the study?
3rd Department of General Surgery, Jagiellonian University Medical College (Poland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Geriatric assessment as a qualification element for elective and emergency cholecystectomy in older patients

Study objectives
1. Frail patients who have qualified for an elective cholecystectomy can be safely operated upon
2. Frail patients who have qualified for an emergency cholecystectomy have higher postoperative morbidity and mortality

Ethics approval required
Old ethics approval format

Ethics approval(s)
Jagiellonian University Medicall College approved the study, 22/05/2014, ref: KBET/128/B/2014

Study design
Observational case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cholecystitis

Interventions
All included patients will be assessed using the Geriatric Assessment, which will be performed on the day of admission by trained physicians or, for emergency patients, by trained physicians or nurses. The GA comprises the validated instruments evaluating functional (Activities of Daily Living - ADL, Instrumental Activities of Daily Living - I-ADL), cognitive (Blessed Orientation-Memory-Concentration Test - BOMC and Clock Drawing Test - CDT), depressive (Geriatric Depression Scale - GDS), nutritional (Mini Nutritional Assessment - MNA) and polypharmacy status (number of drugs taken by the patient) with the range and the literature-based cut-off scores. A cumulative deficit model of frailty will be used. The equally weighted deficits, as a measure of accumulated vulnerability, included ADL/IADL, Geriatric Depression Score, BOMC /CDT, the Mini-Nutritional Assessment, CCS, and the Polypharmacy Assessment. The functional (ADL/IADL) and cognitive domains (BOMC/CDT) will be considered abnormal if one of the assessment tools showed literature-based impairment. The detection of deficits in two or more GA domains indicates an increased risk of disability or death and is used as the cut-off score for the GA set and also as the definition of frailty.

Participation in the study does not change anything in the treatment plan, surgery and postoperative rehabilitation. Enrolled patients will undergo elective/emergency laparoscopic or open cholecystectomy (decision of the surgeon and anesthesiologist). All operations will be performed by residents under the direct supervision of a consultant (who also served as the first assistant) or by the consultants themselves. Laparoscopic cholecystectomy will be performed using a standard three- or four-port technique and all emergency patients were treated surgically within 24 h after admission. Severity grading for the acute cholecystitis patients is

according to the 2013 Tokyo Guidelines. The postoperative follow-up regarding postoperative morbidity and mortality will last for 30-days.

Intervention Type
Other

Primary outcome measure
1. Post-operative complications, defined as any event occurring within 30 days of surgery that required treatment not routinely applied in the post-operative period, is measured through telephone interviews and clinic visits at 30 days post-surgery
2. Post-operative mortality, defined as death within 30 days after surgery, is measured using review of medical records or contact with the appropriate registry office

Secondary outcome measures
Length of hospital stay, defined as the time between the day of admission until discharge from hospital, is measured through medical record review.

Overall study start date
01/01/2013

Completion date
01/03/2015

Eligibility

Key inclusion criteria
Elective patients:
1. Age 65 years or older
2. Symptomatic and sonographically detected cholelithiasis
3. Qualified for elective cholecystectomy (symptomatic and sonographically detected cholelithiasis without any signs of inflammation)
4. Provision of informed consent to participate

Emergency patients:
1. Age 65 years or older
2. Acute cholecystitis according to the 2013 Tokyo Guidelines
3. Qualified for emergency cholecystectomy (acute cholecystitis according to the 2013 Tokyo Guidelines operated within 24 hours after admission to the surgical department)
4. Provision of informed consent to participate

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants

60 elective and emergency patients

Total final enrolment
126

Key exclusion criteria
1. Patients with pancreatitis
2. No consent at the time of surgery

Date of first enrolment
22/05/2014

Date of final enrolment
15/12/2015

Locations

Countries of recruitment
Poland

Study participating centre
Jagiellonian University Medical College
3rd Department of General Surgery
Pradnicka str. 35-37
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Sponsor information

Organisation
3rd Department of General Surgery Jagiellonian University Medical College

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03bqmcz70

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
3rd Department of General Surgery Jagiellonian University Medical College

Results and Publications

Publication and dissemination plan
Publication in a peer reviewed journal.

Intention to publish date
30/09/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/07/2016	30/11/2020	Yes	No