

# Study on frail patients undergoing elective and emergency cholecystectomy

<b>Submission date</b> 30/06/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/11/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## 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?

Dr Jakub Kenig

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Jakub Kenig

### Contact details

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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 Medical 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

Kraków

Poland

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## **Sponsor information**

**Organisation**

3rd Department of General Surgery Jagiellonian University Medical College

**Sponsor details**

Pradnicka 35-37

Krakow

Poland

31-202

**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?
<a href="#">Results article</a>	results	29/07/2016	30/11/2020	Yes	No