ISRCTN83787412 https://doi.org/10.1186/ISRCTN83787412

Assessment of the preoperative education on pain after outpatient surgery to remove the gallbladder

Submission date
21/01/2015

Recruitment status
No longer recruiting

Registration date
23/03/2015

Overall study status
Completed

Last Edited
15/02/2018

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Surgery for cholelithiasis (hard deposits or gallstones in the gallbladder) has traditionally been an inpatient procedure. The introduction of laparoscopic cholecystectomy (surgical removal of the gallbladder with keyhole surgery) radically changed the treatment of cholelithiasis and is now regarded as the best treatment for benign gallbladder disease. According to the results of the first published study of outpatient laparoscopic cholecystectomy in 1990, 45% of the patients could be treated as outpatients with minimum complications, especially in young patients with no history of abdominal surgery. Several studies have shown that outpatient laparoscopic cholecystectomy is reliable and effective and has a high degree of patient satisfaction and perceived quality. However, a high proportion of admissions have been attributed to the appearance of postoperative nausea and pain in some cases. Early research on the benefits of preoperative education of patients were reported in 1958, showing that preoperative information about the various aspects of the operation and expectations reduces patients' stress. Other studies since then have shown that patients who had received preoperative information required less analgesia (pain relief) and recovered faster than did those who had not received such information. When patients are scheduled for laparoscopic cholecystectomy for cholelithiasis, they only receive information about the surgical technique and the type of hospitalisation. The aim in this study is to increase the information that is offered to patients by an educational nurse before the surgery and assess the effect on nausea, pain and unwanted readmissions, illness, quality of life, and patient satisfaction after surgery.

Who can participate?
Patients aged 18–75 years old needing surgery for cholelithiasis.

What does the study involve?
Patients will be randomly allocated to one of two groups. Patients in the study group will receive preoperative information about all the proceedings and after-surgery treatments by the education nurse. The control group will receive conventional information about laparoscopic cholecystectomy.

What are the possible benefits and risks of participating?
The possible benefits are faster recovery after surgery and the need for less pain relief. Risks were not provided at the time of registration.

Where is the study run from?
University Hospital Joan XXIII (Spain)

When is the study starting and how long is it expected to run for?
From May 2014 to June 2015

Who is funding the study?
University Hospital Joan XXIII (Spain)

Who is the main contact?
Dr Aleidis Caro

Contact information

Type(s)
Scientific

Contact name
Dr Aleidis Caro

ORCID ID
http://orcid.org/0000-0001-6151-3879

Contact details
Merce Rodoreda Street
11, B 2º1ª
Tarragona
Spain
43007

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
COLE_HJ23

Study information

Scientific Title
Effect of the preoperative education on pain after ambulatory laparoscopic cholecystectomy: a randomised controlled double-blind trial

Study objectives
Patients who have received preoperative education will have reduced anxiety related to surgery because they will have been better informed of the symptoms that can occur after surgery; these informed patients could control the postoperative symptoms better and could be operated on an ambulatory regimen with higher levels of satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Clinical Research of the University Hospital Joan XXIII (Spain), 09/04/2014, ref: CEIC 26/2014

Study design
Randomised controlled double-blind single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Postoperative pain and quality of life

Interventions
1. Patients in the study group will receive preoperative information about all the proceedings and post operative treatments by the education nurse.
2. Patients in the control group will receive conventional information about laparoscopic cholecystectomy.

Intervention Type
Other

Primary outcome measure
Postoperative pain related, measured using the visual analogue scale (VAS), at the immediate postoperative time, at 6 postoperative hours, at 24 hours, 7 days and 30 days

Secondary outcome measures

1. Postoperative nausea, measured by questioning the patient at the immediate postoperative time, at 6 postoperative hours, at 24 hours, 7 days and 30 days
2. Intraoperative morbidity, measured by Clavien-Dindo classification at 30 days
3. Postoperative morbidity, measured by Clavien-Dindo classification at 30 days
4. Unexpected admissions
5. Time to return to normal work activity, measured by questioning the patient at 30 days
6. Patient satisfaction, measured by Satisfaction Test especifically designed at preoperative and 30 days postoperative
7. Quality of life, measured by SF-12 Quality of Life Test at preoperative and 30 days postoperative

Overall study start date
01/02/2014

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Age 18–75 years old
2. American Society of Anesthesiology (ASA) scores I and II
3. Ambulatory surgery criteria: 30 minutes proximity to the hospital, living with family and telephone at home
4. Patient acceptance for ambulatory surgery
5. Symptomatic cholelithiasis or chronic cholecystitis
6. Liver enzymes and bilirubin within normal ranges
7. No previous supramesocolic surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
62 patients, two clusters with 31 patients each

Key exclusion criteria
1. ASA score III or IV
2. No ambulatory surgery criteria
3. No patient acceptance for ambulatory surgery
4. Difficulty of instruction comprehension

5. Difficulty for airway intubation
6. Co-morbidity
7. Haemodialysis
8. Congestive heart failure
9. Coagulopathy
10. Body-mass index >35 kg/m2

Date of first enrolment
09/04/2014

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
Spain

Study participating centre
University Hospital Joan XXIII
4th Doctor Mallafre Guasch Street
Tarragona
Spain
43007

Sponsor information

Organisation
University Hospital Joan XXIII

Sponsor details
General and Digestive Surgery Department
4th Doctor Mallafre Guasch Street
Tarragona
Spain
43007

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05s4b1t72

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Fundació Hospital Joan XXIII (Spain)

Results and Publications

Publication and dissemination plan
The study results will be presented in conference papers and publications in scientific journals

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No