

The effect of bag extraction in the prophylaxis of wound infection in laparoscopic cholecystectomy

Submission date 10/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/12/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/06/2017	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Laparoscopic (keyhole) cholecystectomy is a surgical procedure where several small cuts (incisions) are made in the abdomen to access and remove the gallbladder. There is a lack of evidence about whether using a bag to extract the gallbladder reduces surgical site infection. Therefore the aim of this study is to assess the effectiveness of bag extraction of the gallbladder at preventing surgical site infection.

Who can participate?

Adult patients undergoing laparoscopic cholecystectomy

What does the study involve?

Participants are randomly allocated to have their gallbladder removed either using a bag or without using a bag. Surgical site infections, complications (hernia) and costs are compared between the two groups.

What are the possible benefits and risks of participating?

The use of a bag may reduce the chance of a surgical site infection. No side effects are expected.

Where is the study run from?

Parc Sanitari Sant Joan de Déu (Spain)

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

January 2011 to December 2012

Who is funding the study?

Parc Sanitari Sant Joan de Déu (Spain)

Who is the main contact?

Dr David Parés

Contact information

Type(s)

Scientific

Contact name

Dr David Parés

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2011-01

Study information

Scientific Title

A prospective, randomised control trial of the effect of bag extraction in the prophylaxis of wound infection in laparoscopic cholecystectomy

Study objectives

The use of bag to extract specimen during laparoscopic cholecystectomy will diminish the rate of wound infection on wound trocar site.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Comité de Ètica Investigació Clínica, January 2011, ref: 2010-Parés Study

Study design

Single-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Choleitis/laparoscopic cholecystectomy

Interventions

The use of bag to extract specimen (gallbladder) after operation versus not using the bag (standard protocol).

At the end of the surgical intervention and after randomization, a bag will be used to extract the specimen for the umbilicus port site wound.

Intervention Type

Procedure/Surgery

Primary outcome measure

Surgical site infection

Secondary outcome measures

1. Port site complications (hernia)
2. Economic analysis

Overall study start date

01/01/2011

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Adult patients
2. Elective surgery of laparoscopic cholecystectomy

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Open specimen intraoperatively
2. Acute cholecystitis finding intraoperatively

Date of first enrolment

01/01/2011

Date of final enrolment

31/12/2012

Locations**Countries of recruitment**

Spain

Study participating centre

Parc Sanitari Sant Joan de Déu

Sant Boi de Llobregat (Barcelona)

Spain

08830

Sponsor information**Organisation**

Saint John of God Health Park (Parc Sanitari Sant Joan de Deu) (Spain)

Sponsor details

c/o David Parés MD, PhD

Department of Surgery

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Barcelona

Spain

08830

Sponsor type

Hospital/treatment centre

Website

<http://www.pssjd.org/ca-es/Paginas/default.aspx>

ROR

<https://ror.org/02f3ts956>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Saint John of God Health Park (Parc Sanitari Sant Joan de Deu) (Spain)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017		Yes	No