

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

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

Parc Sanitari Sant Joan de Déu  
C/ Cami Vell de la colònia 25  
Sant Boi de Llobregat (Barcelona)  
Spain  
08830

# 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  
C/ Cami vell colonia 25  
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?
<a href="#">Results article</a>	results	01/01/2017		Yes	No