

# PADULAP study: To compare postoperative and pathologic results between open and laparoscopic approach for pancreaticoduodenectomy

<b>Submission date</b> 23/07/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/08/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/08/2019	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Pancreaticoduodenectomy (PD) is a major surgical operation involving the pancreas, duodenum and other organs, and is one of the most challenging operations that can be done by laparoscopy (a type of surgical procedure that allows a surgeon to access the inside of the abdomen and pelvis without having to make large cut in the skin). However, it is an operation performed by open surgery by most of the groups interested in pancreatic surgery worldwide and only a few groups have tried to do it by laparoscopy, but the interest in laparoscopic PD is quickly increasing. It is assumed that the advantages of the laparoscopic approach, well known and established for other surgical procedures, may also be applicable for PD. In recent studies, laparoscopic distal pancreatectomy has shown some advantages compared to the open surgery approach in terms of length of stay, blood transfusions and postoperative complications. It is expected that, for groups with experience in laparoscopic and pancreatic surgery, these advantages will be the same for PD.

### Who can participate?

This study aims to recruit about 66 patients, aged 18 and over, both male and female, admitted at Hospital del Mar, Spain, for PD as a standard treatment for their disease.

### What does the study involve?

Participants will be randomly allocated to one of two groups, laparoscopic PD and open PD.

### What are the possible benefits and risks of participating?

The possible benefits for the patients who will participate in the study is that they will have the opportunity of being operated by the laparoscopic approach instead of the open approach with at least the same results.

Since 2006 our group have been performing laparoscopic PD in selected cases. To date we have

operated on 15 patients with similar results to the open approach. No deaths have been recorded in our patients operated by the laparoscopic approach, including those who need conversion to the open procedure.

Where is the study run from?

The study has been set up by the Unit of Hepato-Biliary-Pancreatic Surgery, Department of General and Digestive Surgery, Hospital del Mar, Barcelona, Spain.

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

The study started to recruit patients in January 2013. We aim to enrol 66 patients, which is expected to take four years. Because the main endpoints are length of stay and postoperative results, there is no need for a long follow-up for the study. Nevertheless, most of the patients are operated due to bilio-pancreatic cancer, so they will have the routine follow-up at the hospital for a minimum of five years.

Who is funding the study?

There is no a special source of funding for doing these operations. These are common techniques performed at the Hospital del Mar and covered by the National Spanish Public Health System (Spain).

Who is the main contact?

Ignasi Poves, MD, PhD

ipoves@parcdesalutmar.cat

### **Study website**

[http://www.parcdesalutmar.cat/media/upload/arxiu/cirurgia/recerca/estudiRCT\\_DPC\\_LAP.pdf](http://www.parcdesalutmar.cat/media/upload/arxiu/cirurgia/recerca/estudiRCT_DPC_LAP.pdf)

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Dr Ignacio Poves Prim

### **Contact details**

Hospital del Mar  
Passeig Marítim 25-29  
Barcelona  
Spain  
08003

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ipoves@parcdesalutmar.cat

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

2013/5023/I

## **Study information**

### **Scientific Title**

A randomised trial to compare postoperative and pathologic results between open and laparoscopic approach for pancreaticoduodenectomy

### **Acronym**

PADULAP

### **Study objectives**

As it has been demonstrated for other surgical operations, laparoscopic approach has proved some benefits in front of the open approach in terms of better cosmetic results, shorten hospital length of stay, less pain, less blood transfusion and a faster recovery, while maintaining at least the same postoperative complications rates and oncological results.

Pancreaticoduodenectomy (PD) is one of the most challenging operations, not only for laparoscopic, but for open approach. The hypothesis is that, when performed by surgeons specially trained in both laparoscopic and pancreatic surgery, laparoscopic PD has better results in front of the open PD in terms of blood transfusion and length of stay while maintaining at least equal postoperative complication rates and pathologic results.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

CEIC (Clinical Research Ethical Committee)-Parc de Salut MAR num. 2013/5023/I. Date of approval: 15 March 2013, amendments approved on 15 April 2013.

The Clinical Research Ethical Committee of our centre (CEIC-Parc de Salut MAR) has approved the informed consent form (num. 2013/5023/I) on April 4th 2013.

### **Study design**

Single-centre open randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

**Participant information sheet**

The patient information sheet is given to the patient when accepts to be enrolled in the study and is available on the trial web [http://www.parcdesalutmar.cat/media/upload/arxiu/cirurgia/reerca/estudiRCT\\_DPC\\_LAP.pdf](http://www.parcdesalutmar.cat/media/upload/arxiu/cirurgia/reerca/estudiRCT_DPC_LAP.pdf).

### **Health condition(s) or problem(s) studied**

Patients who require a pancreaticoduodenectomy as a surgical intervention for the radical treatment of their disease

### **Interventions**

Patients who have to be operated of PD will be randomised in two groups, laparoscopic and open approach. Open randomisation has been done using an informatic programme.

The duration of the study is planned for 4 years, minimum follow up of the patients is 2 years.

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Applicable

### **Primary outcome measure**

Length of stay: days (a day will be considered as a night spent in the hospital)

### **Secondary outcome measures**

1. Global complications (Claviens classification of surgical complications adopted for pancreatic surgery) - At 30, 60 and 90 days
2. Severe complications (grades >II in the Claviens classification of surgical complications adopted for pancreatic surgery) - At 30, 60 and 90 days
3. Specific complication related to pancreatic surgery (pancreatic fistula, delayed gastric emptying, post-pancreatectomy haemorrhage) - At 30, 60 and 90 days
4. Blood transfusion (peroperative and total stay) - Peroperative: first 24 h. from the beginning of the surgery, includes intraoperative transfusion. Total: all blood requirements until date of discharge.
5. Oncologic results attending to the quality of the resected specimen (lymph nodes harvested, margins affected)
6. Cost/benefit study. From the beginning of the operation until the day of discharge.

### **Overall study start date**

01/01/2013

### **Completion date**

31/12/2017

## **Eligibility**

### **Key inclusion criteria**

1.  $\geq 18$  years, both sex
2. Patients who have a benign, premalignant or malignant disease in the head of the pancreas, peripancreatic area or bilio-pancreatic confluence, who require a pancreatoduodenectomy as the standard treatment for surgical resection.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Total number of participants is 66 patients. A preliminary analysis of the results will be done every 20 patients enrolled.

**Total final enrolment**

66

**Key exclusion criteria**

1. Pregnancy
2. Tumour involvement of the portal or mesenteric vein requiring vascular resection with vascular reconstruction
3. Clearly hostile abdomen for laparoscopic surgery (multiples previous laparotomies, incisional hernias, complex previous upper GI surgery)
4. Previous chronic disease that can contraindicate the laparoscopic approach (cirrhosis, severe pulmonary disease, etc.)

**Date of first enrolment**

01/01/2013

**Date of final enrolment**

31/12/2017

**Locations****Countries of recruitment**

Spain

**Study participating centre**

Hospital del Mar

Barcelona

Spain

08003

**Sponsor information**

## Organisation

Hospital del Mar (Spain)

## Sponsor details

Passeig Marítim 25-29

Barcelona

Spain

08003

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ipoves@parcdesalutmar.cat

## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/03a8gac78>

# Funder(s)

## Funder type

Government

## Funder Name

There is no a special source of funding for doing these operations. These are common techniques done in Hospital del Mar and covered by the National Spanish Public Health System (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	01/11/2018		Yes	No

