

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

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<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  
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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

2013/5023/1

## 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

## **Study type(s)**

Treatment

## **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(s)

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

## Key secondary outcome(s)

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.

## 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, periampullary area or bilio-pancreatic confluent, who require a pancreatico-duodenectomy as the standard treatment for surgical resection.

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### 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)

**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

## 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
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes