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

Submission date
23/07/2013

Recruitment status
No longer recruiting

Registration date
05/08/2013

Overall study status
Completed

Last Edited
27/08/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Study website
http://www.parcdesalutmar.cat/media/upload/arxius/cirurgia/recerca/estudiRCT_DPC_LAP.pdf

Contact information

Type(s)
Scientific

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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 Reseach Ethical Committee)-Parc de Salut MAR num. 2013/5023/I. Date of approval: 15 March 2013, amendments approved on 15 April 2013.
The Clinical Reseach 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/arxius/cirurgia/recerca/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
Lenght 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 Clavien¡¯s 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 requiriments 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.>=18 years, both sex
2. Patients who have a benign, premalignant or malignant disease in the head of the pancreas, periampulary area or bilio-pancreatic confluent, who require a pancreatico-duodenectomy 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)

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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?
Results article	results	01/11/2018		Yes	No