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To determine whether reconstruction of pancreatic remnant with the stomach after pancreatoduodenotomy can be safe and acceptably decreases the rate of pancreatic fistulas compared with reconstruction with the small bowel

Submission date	Recruitment status	[_] Prospectively registered
20/01/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/02/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/10/2016	Surgery	

Plain English summary of protocol

Background and study aims

Pancreaticoduodenectomy (PD) is surgery to remove part of the pancreas and part of the stomach. It is the best treatment for patients with pancreatic cancer. However, PD can lead to leakage (called pancreatic fistula) with a significant risk of illness and death. It is not known which reconstruction method is to best at reducing the risk of fistula. Pancreaticojejunostomy (PJ) involves connecting the remnant of the pancreas to the middle portion of the small intestine, and is the most commonly used reconstructive method after PD. Pancreaticogastrostomy (PG) involves connecting the remnant of the pancreas to the stomach, and may have a lower risk of fistula. The aim of this study is to compare the rate of fistula and other complications between both methods.

Who can participate?

Patients aged 18 to 80 undergoing PD for pancreatic tumours, chronic pancreatitis (long-term inflammation of the pancreas), or cancer that has spread to the pancreas

What does the study involve?

Participants are randomly allocated to one of two groups. One group undergoes PG surgery while the other group undergoes PJ surgery. Rate of pancreatic fistula, complications, further surgery, illness and death are measured in both groups at the time of hospital discharge and 3 months later.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part, but there may be a lower rate of pancreatic fistula with the PG surgery, which could benefit future patients. Previous studies suggest that PG is at least as safe as PJ.

Where is the study run from?
Hospital Clinico de Valencia and Hospital “Dr Josep Trueta” in Girona (Spain)

When is the study starting and how long is it expected to run for?
February 2008 to February 2013

Who is funding the study?
Instituto de Salud Carlos III (Spain)

Who is the main contact?
Prof. Joan Figueras Felip
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI08621

Study information

Scientific Title

Pancreatogastrostomy vs. pancreatojejunostomy for reconstruction of the pancreatic remnant after pancreatoduodenotomy: a prospective, randomised, controlled, metacentre study

Acronym
PGvsPJ

Study objectives
Pancreato-gastric anastomosis of the pancreas with the stomach after pancreatoduodenotomy presents less incidence of pancreatic fistula than the standard reconstruction with pancreato-jejunostomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Doctor Josep Trueta University Hospital in Girona, 01/02/2008

Study design
Randomised prospective controlled parallel-group multicentre trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Pancreatectomy

Interventions
Group PG: Pancreatogastric anastomois of the pancreatic remnant to the stomach
Group PJ: Pancreatojejunostomy anastomois of the pancreatic remnant to the jejunum

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure

Rate of pancreatic fistula, evaluated at the time of hospital discharge and at 3 months post-operatively. The severity of the PF will be evaluated with the ISGPH score.

Secondary outcome measures
1. Mortality and morbidity
2. Complications graded according to Dindo-Clavien classification
3. Reoperation rate
4. Readmissions and hospital stay
Evaluated at the time of hospital discharge and at 3 months post-operatively.

Overall study start date
22/02/2008

Completion date
28/02/2013

Eligibility

Key inclusion criteria
1. Consecutive patients who will undergo pancreatodudodenectomy (DPC) at Hospital Clinico de Valencia and Hospital Dr Josep Trueta in Girona Spain. Coordinated by Dr Josep Trueta Hospital of Girona
2. Patients aged 18 to 80 years, either sex
3. Pancreatectomy is indicated because of a benign or malignant tumour of the pancreas, chronic pancreatitis or malignant neoplasm of other organs infiltrating the pancreas, provided the parenchyma of the pancreas is suitable for anastomosis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
130 patients

Key exclusion criteria
1. Patients who at the time of surgery are found not resectable
2. Associated resection of other organs, excluding the superior mesenteric vein
3. American Society of Anaesthesiologists (ASA) anesthetic risk 4 as the American Association of Anesthesiologists
4. Pancreatoduodenectomy (PD) for calcifying chronic pancreatitis
5. PD palliative leaving macroscopic tumor
6. Preoperative obstructive jaundice with bilirubin> 300µmol or 15 mg/L

Date of first enrolment
22/02/2008

Date of final enrolment
28/02/2013

Locations

Countries of recruitment
Spain

Study participating centre
Dr Josep Trueta Hospital
Girona
Spain
17007

Sponsor information

Organisation
Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Instituto de Salud Carlos III (Spain) FIS (Registration number PI08621)

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	01/11/2013		Yes	No