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Comparison of laparoscopic and open distal pancreatectomy

Submission date 28/09/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2015	**Overall study status** Completed	
Last Edited 10/03/2023	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The pancreas is a large gland belonging to the digestive system. It produces digestive enzymes (enzymes that break down food) and hormones (for example insulin, the hormone that controls blood sugar levels). Pancreatic cancer is difficult to diagnose in the early stages as symptoms don't usually occur until the disease is at a more advanced stage. One of the main treatments for pancreatic cancer is surgery, where at least part of the pancreas is removed (resected). This can be done as open surgery (traditional surgery where the patient is opened up at the region where the procedure is to be performed) or laparoscopic (or keyhole) surgery. Laparoscopic surgery allows the surgeon to access a region of the inside of the body without having to make the large incisions (cuts) required in open surgery. The incisions made are much smaller and a laparoscope, a optic cable that allows the surgeon to see inside the body, is used to do the operation. This study investigates whether laparoscopic resection of the left side of the pancreas may result in shorter hospital stay and less bleeding than open procedures.

Who can participate?
Patients that are at least 18 years old diagnosed with diseases in the pancreatic body or tail that needs resection.

What does the study involve?
Particiants are randomly allocated to one of two groups. Those in group 1 have an open distal pancreatectomy. Those in group 2 have a laparoscopic distal pancreatectomy. After surgery, the length of hospital stay for all participants are recorded and comparisons are made as to the amount of bleeding after surgery, pain experienced after surgery, quality of life, any complications, costs involved and whether the participants were still alive two years afterwards.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Linköping University Hospital (lead centre) and Kalmar Hospital (Sweden)

When is study starting and how long is it expected to run for?
January 2014 to January 2020

Who is funding the study?
Region Östergötland (Sweden)

Who is the main contact?
Dr Bergthor Björnsson

Contact information

Type(s)
Public

Contact name
Dr Bergthor Björnsson

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
RCT-Laparoscopic vs open distal pancreatectomy in an unselected patient cohort

Study objectives
Laparoscopic distal pancreatectomy (LDP) with or without the use of robot, shortens hospital stay and reduces bleeding compared to open distal pancreatectomy (ODP) in unselected patients undergoing distal pancreatectomy with or without splenectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Regionala etikprövningsnämnden i Linköping (The regional ethics board for South-east Sweden), ref: 2015/39-31

Study design
Prospective, randomized comparison of laparoscopic vs. open distal pancreatectomy, multicentre

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pancreatic tumors

Interventions
Two arms:
1. Laparoscopic distal pancreatectomy
2. Open distal pancreatectomy

Intervention Type
Procedure/Surgery

Primary outcome measure
Length of stay in hospital after laparoscopic- and open distal pancreatectomy

Secondary outcome measures
1. To compare perioperative bleeding during LDP and ODP, measured after operation
2. To compare postoperative pain after LDP and ODP, measured 3 times/day during hospital stay with Visual analouge scale
3. To compare the use of analgetics after LDP and ODP, measured at discharge, amount of drugs given
4. To evaluate quality of life postoperatively after LDP and ODP, measured 5-6 weeks postoperatively as well as 6, 12 and 24 months after operation. Tools for measurement: EORTC QLQ-C30 to which is added the PAN26 module and EQ-5D.
5. To analyze costs associated with LDP and ODP. Measured as direct (hospital cost) after discharge a combination of actual cost and schablon is used
6. To compare complications in LDP and ODP measured up to 90 Days after operation according to Clavien-Dindo classification as well as comprehensive complication index
7. To evaluate survival, measured 2 years after operation

8. Oncological quality of resection measured by PAD assessment as number of investigated lymphnodes and tumor marginal in mm

Overall study start date
01/01/2014

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1.Patients with lesion in the body or tail of the pancreas demanding surgery (indication set by multidisciplinary conference)
2. Operable patient (as the local preoperatively evaluation dictates)
3. Possibility to achieve R0-resection without resection of additional organs (besides the spleen)
4. Patients with performance status 0-2 according to WHO scale
5. Written informed consent.
6. Age > 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Pregnancy and/or lactation
2. Patients being unable to comply with the protocol for reasons of language or cognitive function
3. Preoperatively defined need to resect other organs than pancreas and spleen
4. Preoperatively defined division line of pancreas to the right of the SMV

Date of first enrolment
01/10/2015

Date of final enrolment
18/02/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University Hospital (lead centre)
Linköping
Sweden
58185

Study participating centre
Kalmar Hospital
Lasarettsvägen 1
Kalmar
Sweden
39185

Sponsor information

Organisation
Region Östergötland

Sponsor details
Linköping University Hospital
Linköping
Sweden
58185

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0326gsy75

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Region Östergötland (Sweden)

Results and Publications

Publication and dissemination plan

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Bergthor Björnsson (bergthor@bjornsson@liu.se).
Type of data: variables published
When the data will become available and for how long: after publication of primary endpoint, unclear how long
By what access criteria data will be shared including with whom: shared for the purposes of doing IPDMA
For what types of analyses: IPDMA
By what mechanism: according to agreement
Whether consent from participants was obtained: informed consent (written) was obtained
Comments on data anonymisation: all data is anonymous
Any ethical or legal restrictions, any other comments: no

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/06/2019	17/06/2019	Yes	No
Results article	results	01/09/2020	08/04/2020	Yes	No
Other publications		07/03/2023	10/03/2023	Yes	No