Comparison of laparoscopic and open distal pancreatectomy

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
28/09/2015		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/09/2015	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
17/10/2025	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

Linköping University Hospital Surgical Department Linköping Syria 58185

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?
<u>Protocol article</u>	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
Results article		05/05/2023	17/10/2025	Yes	No