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Early or late drain removal after pancreatic surgery

Submission date
10/04/2018

Recruitment status
Recruiting

Registration date
11/05/2018

Overall study status
Ongoing

Last Edited
08/06/2023

Condition category
Surgery

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Abdominal drains are sometimes placed during surgery in order to minimize the risk from bowel contents or other dangerous fluids collecting in the abdomen. This practice has been reduced in many branches of surgery during the last decades as the benefit of this treatment is questionable and the risk associated with having drains (plastic tubes) inside the abdomen is inevitable. When it comes to pancreatic surgery the risk from leakage of pancreatic juice into the abdominal cavity is high and the routine use of drains is therefore the standard of care. The drains are usually left in place for a minimum of 3 days after surgery and then removed if no signs of leakage are found. There are results available from earlier research indicating that drains can safely be removed as early as one day after surgery if no leakage is present. The aim of this study is to find out whether early drain removal after pancreatic surgery shortens hospital stay.

Who can participate?
Patients undergoing removal of the pancreatic head and associated tissue (Whipple operation) and with normal concentration of drain amylase (pancreatic enzyme) the day after surgery

What does the study involve?
Participants are randomly allocated to undergo either early drain removal (one day after surgery) or conventional drain removal (at earliest three days after surgery). Their treatment is otherwise according to hospital standards and the follow up (within the study) is 90 days. Length of hospital stay is measured at discharge.

What are the possible benefits and risks of participating?
The possible benefits of participating are that early drain removal may shorten hospital stay and reduce the risk of drain-associated complications. The main risk is that the normal drain amylase on the day after surgery may not completely exclude leakage and therefore longer drain treatment could be of value.

Where is the study run from?
1. Linköping University Hospital (Sweden)
2. Skånes University Hospital (Sweden)

3. Sahlgrenska University Hospital (Sweden)
4. Oslo University Hospital (Norway)

When is the study starting and how long is it expected to run for?
April 2017 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Bergthor Björnsson
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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
DrainRemovalStudy1.1

Study information

Scientific Title
Post-operative drainage after pancreaticoduodenectomy: a randomized controlled trial of early drain removal vs late drain removal

Study objectives
Early drain removal after pancreatoduodenectomy shortens hospital stay.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board, Linköping, Sweden, 16/10/2017, ref: Dnr 2017/310-31

Study design
Prospective randomized study

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Pancreatic disease treated with pancreatoduodenectomy

Interventions
The randomisation will be by online websolution after the results of drain amylase POD 1 are known and within the inclusion limits of the study. There are two treatment arms:
1. Early drain removal (POD 1)
2. Conventional drain removal earliest on POD 3 when no pancreatic fistula exist according to the definition of POPF (postoperative pancreatic fistula)
The treatment will otherwise be according to hospital standards and the follow up (within the study) is 90 days.

Intervention Type
Procedure/Surgery

Primary outcome measure
Hospital stay, measured at discharge

Secondary outcome measures
1. Overall morbidity rate classified as Clavien-Dindo ≥3a within 90 days
2. Mortality rate (in-hospital, 30 and 90 days)
3. Overall morbidity rate as classified by Clavien-Dindo within 90 days
4. Fistula rate according to ISGPF (grade B and C fistulas) within 90 days
5. Intraabdominal abscess rate within 90 days
6. Wound infection rate within 90 days
7. Delayed gastric emptying according to ISGPF within 90 days
8. Postpancreatectomy bleeding according to ISGPF within 90 days

9. Need of interventional radiology within 90 days
10. Need for reoperation within 90 days
11. Readmission rate within 90 days

Overall study start date
01/04/2017

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Patients planned for pancreatoduodenectomy with high risk for anastomosis leakage

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
280

Key exclusion criteria
Low risk for anastomosis leakage

Date of first enrolment
01/09/2018

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
Norway

Sweden

Study participating centre
Linköping University Hospital
Linköping
Sweden
58185

Study participating centre
Skånes University Hospital
Lund
Sweden
22242

Study participating centre
Sahlgrenska University Hospital
Gothenburg
Sweden
41345

Study participating centre
Oslo University Hospital
Oslo
Norway
0372

Sponsor information

Organisation
Region Östergotland

Sponsor details
Garnisonvägen
Linköping
Sweden
58185

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0326gsy75

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of the primary endpoint will be published in a high-impact peer reviewed journal within 1 year after inclusion of the last patient. Further analysis of secondary endpoints will be done thereafter.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date. Additional documents (such as study protocol, statistical analysis plan) will not be made available online at this time.

IPD sharing plan summary
Data sharing statement to be made available at a later date