

Distal pancreatectomy, minimally invasive or open, for malignancy

Submission date 16/04/2018	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 19/04/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/10/2025	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Cancer of the body or tail (or distal part) of the pancreas is a devastating disease with a 5-year survival of 20% after intended curative treatment. Surgery is the only potentially curative treatment for pancreatic cancer but the postoperative morbidity (30%) and mortality rates (3-5%) are high. Minimally invasive (keyhole) surgery is on the rise worldwide. These procedures are performed through tiny incisions instead of one large opening. Several studies suggest that minimally invasive surgery is superior to conventional open surgery in terms of post-operative pain, morbidity and length of hospital stay. The introduction of minimally invasive pancreatic surgery has been much slower than for other surgical procedures, although the number of minimally invasive pancreatic resections performed has increased significantly in the past decade. Minimally invasive distal pancreatectomy (MIDP) has been shown in recent systematic reviews to have excellent outcomes in benign or premalignant disease concerning intraoperative and postoperative outcomes (i.e. blood loss, spleen preservation, postoperative morbidity, postoperative recovery) when compared to open distal pancreatectomy (ODP). However high-quality comparative studies of minimally invasive versus open surgery for distal pancreatic malignancies are scarce. Surgeons are faced with the decision to perform a MIDP or ODP in a patient with pancreatic cancer without clear evidence to support them. Especially oncological safety is not clearly demonstrated. At this moment a substantial amount of pancreatic cancer patients do not receive minimally invasive surgery and consequently may not benefit from possible shorter time to recovery and better quality of life after surgery, which especially for these patients with poor prognosis could be of substantial value. The aim of this study is to provide evidence on the potential benefits of minimally invasive surgery in patients with cancer of the body or tail of pancreas.

Who can participate?

Patients aged 18 or over who require resection of their distal pancreas for pancreatic ductal adenocarcinoma (PDAC), a type of pancreatic cancer

What does the study involve?

Participants are randomly allocated to either open or minimally invasive surgery. They receive a large abdominal dressing directly after surgery to mask their treatment (minimally invasive or open) by covering all incisions. This abdominal dressing is removed when recovery is complete,

at day 5 after the operation or for medical reasons, such as for example suspicion of a wound infection. Participants complete quality of life questionnaires at the start of the study, and 1, 3 and 6 months after their surgery. Survival rates are calculated for 1, 2 and 3 year after the surgery.

What are the possible benefits and risks of participating?

Minimally invasive surgery may reduce the length of the hospital stay and improve postoperative morbidity and mortality. There are no added risks.

Where is the study run from?

This study is led by the University Hospital Southampton NHS Foundation Trust (UK) and Amsterdam UMC (The Netherlands). Patients are recruited by 38 centres from 12 countries.

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

January 2018 to May 2024

Who is funding the study?

1. The Dutch Digestive Foundation (The Netherlands)
2. Academic Medical Center, Amsterdam (The Netherlands)
3. Ethicon Endo-surgery Inc.
4. Medtronic

Who is the main contact?

1. Prof. Mohammed Abu Hilal
2. Prof. Marc Besselink

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04483726

Protocol serial number

The United Kingdom: RHMGSU0230, CPMS ID 37581; The Netherlands: NL63299.018.17

Study information

Scientific Title

Distal pancreatectomy, minimally invasive or open, for malignancy (DIPLOMA): a pan-European, randomized controlled, multicenter, patient blinded, non-inferiority trial

Acronym

DIPLOMA

Study objectives

The trialists hypothesise that minimally invasive (laparoscopic and robot-assisted) distal pancreatectomy (MIDP) provides similar oncologic efficacy (i.e. microscopically radical resection margins (R0)) to open distal pancreatectomy (ODP) when performed in patients affected by PDAC.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. The United Kingdom: South West - Frenchay Research Ethics Committee, 08/03/2018, ref: 18/SW/0047

2. The Netherlands: Medical Ethics Review Committee of Amsterdam UMC, location Academic Medical Center, 25/01/2018, ref: NL63299.018.17

For the following countries, separate ethical approvals have been obtained: Belgium, France, Germany, Italy, Norway, Russia, Slovenia, Spain, Sweden, Finland and the USA.

Primary study design

Interventional

Study design

Multicenter; Randomized 1:1 ratio; Interventional; Patient-blinded

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Proven or suspected pancreatic ductal adenocarcinoma (PDAC) in the pancreatic body or tail suitable for elective upfront distal pancreatectomy

Interventions

This study is designed for patients with an indication for distal pancreatectomy because of proven or suspected PDAC in the pancreatic body or tail. After inclusion, patients are randomly allocated in a 1:1 ratio to Minimally Invasive Distal Pancreatectomy or Open Distal Pancreatectomy, stratified by hospital volume and tumor involvement of other organs besides the pancreas and spleen. Randomization will take place as soon as the distal pancreatectomy can be planned. Patients will have a pre-surgery assessment conform local protocol.

Patients are blinded for the type of surgery they will receive. Patients will receive a large 40cm x 40cm abdominal dressing directly after surgery to mask their treatment (minimally invasive or open) by covering all incisions. This abdominal dressing will be removed when all criteria for functional recovery are met, and may be removed earlier when it's day 5 postoperatively or for medical reasons, such as for example suspicion of a wound infection. If earlier inspection is required, attempts are made to maintain patient blinding. This blinding has been proven successfully in previous multicentre (European) trials. A complete double-blinding, including medical and nursing ward staff, is considered not feasible.

Patients are asked to complete QoL questionnaires at baseline, 1 month, 3 months and 6 months after their surgery. Survival rates will be calculated for 1, 2 and 3 year postoperative.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Microscopically radical resection margin (R0) (these can be in the transection margin of the pancreas but also in the anterior, superior, posterior, inferior margins, i.e. circumferential margins); Timepoint: postoperative

Key secondary outcome(s)

1. Intraoperative parameters (operative time, blood loss, blood transfusion and conversion)
2. Postoperative parameters (complications, mortality, re-interventions)
3. Pathology parameters (tumor size, lymph node retrieval, positive nodes, invasion, grading and staging)
4. Hospitalization parameters (time to functional recovery [measured daily using the functional recovery checklist], total hospital stay, readmission, intensive care admission)
5. Oncology parameters (use of (neo-)adjuvant chemotherapy, survival at 1, 2 and 3 years postoperative)
6. Quality of life, measured using the EORTC QLQ-30 and PAN-26 and EQ-5D-5L questionnaires at baseline and 1, 3 and 6 months postoperative
7. Costs

Completion date

05/05/2024

Eligibility

Key inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:

1. Age ≥ 18 years
2. Elective indication for distal pancreatectomy for proven or suspected* PDAC
3. Upfront (without induction/downsizing radio- or chemotherapy) resectable PDAC in the pancreatic body or tail**
4. The tumor can be radically resected via both minimally invasive or open surgery according to the local treating team***
5. The patient is fit to undergo both open and minimally invasive distal pancreatectomy

*Pathology proof is not mandatory for two reasons, first it is not common practice in distal cancers to have this proof, so the decision for minimally invasive or open surgery will after the trial also depend on the 'suspected' diagnosis and second, there are even some concerns about the safety of endoscopic fine needle aspiration of distal pancreatic cancers with theoretical risk of peritoneal seeding

**Malignant degenerated cysts are not allowed in the study. Neoadjuvant chemotherapy is only allowed in case of an upfront resectable tumor (neoadjuvant)

**Multivisceral resections are allowed if, according to the local treating team, feasible with both, a minimally invasive and open approach

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

258

Key exclusion criteria

Current exclusion criteria as of 19/05/2020:

Patients that meet any of the following criteria will be excluded from participation in this study:

1. American Society of Anesthesiologists classification >3
2. A medical history of chronic pancreatitis (according to the M-ANNHEIM criteria)
3. Second malignancy necessitating resection during the same procedure
4. Distant metastases (M1) including involved distant lymph nodes
5. Tumor involvement or abutment of major vessels (celiac trunk*, mesenteric artery or portomesenteric vein);

6. Pregnancy
7. Participation in another study with interference of study outcomes

*The celiac trunk should be 5mm clear from tumor

Previous exclusion criteria:

Patients that meet any of the following criteria will be excluded from participation in this study:

1. ASA >3 (see appendix 17.3.2)
2. A medical history of chronic pancreatitis (according to the M-ANNHEIM criteria, see Appendix for detailed definition)
3. Second malignancy necessitating resection during the same procedure
4. Radiotherapy because of pancreatic cancer prior to distal pancreatectomy
5. Distant metastases (M1) including involved distant lymph nodes
6. Tumor involvement or abutment of major vessels (celiac trunk*, mesenteric artery or portomesenteric vein);
7. Pregnancy
8. Participation in another study with interference of study outcomes

*The celiac trunk should be 5mm clear from tumor

Date of first enrolment

01/05/2018

Date of final enrolment

07/05/2021

Locations

Countries of recruitment

United Kingdom

England

Wales

Belgium

France

Germany

Italy

Netherlands

Norway

Russian Federation

Slovenia

Spain

Sweden

United States of America

Study participating centre

Amsterdam UMC

Amsterdam

Netherlands

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Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

-

Study participating centre

Radboud University Medical Center

Nijmegen

Netherlands

-

Study participating centre

Catharina Hospital

Eindhoven

Netherlands

-

Study participating centre

Utrecht Medical Center

Utrecht

Netherlands

-

Study participating centre

St Antonius Hospital

Nieuwegein

Netherlands

-

Study participating centre

University Hospital Southampton

Southampton

United Kingdom

SO16 6YD

Study participating centre

Morrison Hospital

Swansea

United Kingdom

SA6 6NL

Study participating centre

Oxford University Hospital

Oxford

United Kingdom

OX3 9DU

Study participating centre

King's College Hospital

London

United Kingdom

SE5 9RS

Study participating centre

University Hospital Birmingham

Birmingham

United Kingdom

B15 2TH

Study participating centre

The Freeman Hospital

Newcastle Upon Tyne

United Kingdom

NE7 7DN

Study participating centre
Lübeck University Hospital
Lübeck
Germany

-

Study participating centre
Universitätsklinikum Freiburg
Freiburg
Germany

-

Study participating centre
Universitätsklinikum Erlangen
Erlangen
Germany

-

Study participating centre
Heidelberg University Hospital
Heidelberg
Germany

-

Study participating centre
Oslo University Hospital and Institute for Clinical Medicine
Oslo
Norway

-

Study participating centre
Linköping University
Linköping
Sweden

-

Study participating centre

Verona University Hospital

Verona

Italy

-

Study participating centre

Università de Pisa

Pisa

Italy

-

Study participating centre

Pederzoli Hospital

Peschiera

Italy

-

Study participating centre

S. Orsola-Malpighi Hospital

Bologna

Italy

-

Study participating centre

San Raffaele Hospital IRCCS

Milan

Italy

-

Study participating centre

Niguarda Ca' Granda Hospital

Milan

Italy

-

Study participating centre

Humanitas University Hospital

Milan

Italy

-

Study participating centre

University Hospital Pavia

Pavia

Italy

-

Study participating centre

Hospital of Beaujon

Beaujon

France

-

Study participating centre

Centre Hospitalier Regional D'Orleans

Orleans

France

-

Study participating centre

Hopital Saint Eloi

Montpellier

France

-

Study participating centre

Institut Mutualiste Montsouris

Paris

France

-

Study participating centre

Hospital del Mar

Barcelona

Spain

-

Study participating centre

Hospital Clínic de Barcelona

Barcelona

Spain

-

Study participating centre

Hospital Josep Trueta

Girona

Spain

-

Study participating centre

Hospital Universitari Vall d'Hebron

Barcelona

Spain

-

Study participating centre

Ghent University Hospital

Ghent

Belgium

-

Study participating centre

University Medical Center Ljubljana

Ljubljana

Slovenia

-

Study participating centre

Moscow Clinical Scientific Center

Moscow

Russian Federation

-

Study participating centre

Virginia Mason Medical Center

Seattle

United States of America

-

Study participating centre

Poliambulanza Foundation Hospital

Brescia

Italy

-

Sponsor information

Organisation

University Hospital Southampton NHS Foundation Trust

Organisation

Academic Medical Center

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Charity

Funder Name

Maag Lever Darm Stichting; Grant Codes: I 17-08

Alternative Name(s)

Dutch Liver Foundation, Stomach Liver Bowel Foundation, MLDS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Academisch Medisch Centrum

Alternative Name(s)

Academic Medical Center, Centre Médical Académique, ACADEMISCH MEDISCH CENTRUM AMSTERDAM, Academic Medical Center (Amsterdam), AMC

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Results and Publications

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.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Long-term results at 3 years (36 months)	06/07/2023	17/07/2023	Yes	No
Results article		08/10/2025	20/10/2025	Yes	No
Protocol article		09/09/2021	13/09/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information			11/11		
	Participant information sheet				

[sheet](#)

[Study website](#)

Study website

11/11/2025	/2025	No	Yes
11/11/2025	11/11/2025	No	Yes