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Comparing two slicing techniques in the pathological assessment of pancreas specimens in persons who undergo a Whipple resection

Submission date	Recruitment status	[_] Prospectively registered
25/04/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/10/2022	Cancer	

Plain English summary of protocol

Background and study aims
This study compares two techniques to assess the tumor after surgery on the pancreas. The goal is to find the best technique to determine the origin of the tumor/cancer.

Who can participate
All patients that undergo resection of the pancreas head (pancreatoduodenectomy) for a (suspected) tumor or cancer older than 18 years.

What does the study involve
Two techniques to investigate the pancreas after surgery will be compared. These two techniques are commonly used worldwide but have not been compared so far.

What are the possible benefits and risks of participating
Since the tumor is only investigated after surgery, there are no adverse effects for a participating individual. Investigation of the tumor is routinely done and does not interfere with the patients treatment after surgery.

Where is the study run from
The lead center is the Amsterdam UMC, location AMC, and in total we expect 4-5 other Dutch centers to collaborate.

Who is funding the study
Investigator initiated and funded.

Who is the main contact
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
W18_110 # 18.139

Study information

Scientific Title
Axial slicing versus bivalving of the pancreatic head in the pathological examination of pancreatoduodenectomy specimens: a multicenter, randomized, controlled study

Acronym
APOLLO

Study objectives
Bivalving of the pancreatic head provides more accurate determination of the origin of the primary tumor compared to axial slicing of the pancreatoduodenectomy specimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/04/2018, Medical Ethics Review Committee of Academic Medical Center Amsterdam (Amsterdam UMC, location AMC, Ethics Committee, PO Box 22660, 1100 DD, Amsterdam, Netherlands; s.vanroesse@amc.uva.nl; +31 20 566 9111), ref: W18_110 # 18.139

Study design
Multicenter randomized controlled 1:1 ratio superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Patients that undergo elective pancreatoduodenectomy for a malignant or premalignant periampullary lesion

Interventions
Participants will be randomised to one of two treatment arms:
1. Axial slicing according to Verbeke: Parallel margins (en face) from the pancreatic neck margin, proximal distal bile duct margin and enteric proximal and distal margin will be taken. Fixation of the specimen in formalin, after that serial specimen slicing in the axial plane in slices of 3-5 millimeter thick after fixation.
2. Bivalving of the pancreatic head according to Adsay: The main pancreatic duct and common bile duct are probed, and the specimen is sliced along the plane defined by both probes and both ducts are longitudinally opened, i.e. bivalving of the pancreatic head.

Remaining part of the pathological examination will be according to local protocols. Macroscopic photos will be taken from the specimens and an expert panel of pathologists will assess the photos.

The randomization process is done centrally by a computer-based system, stratified for center and neoadjuvant treatment (yes/no).

Intervention Type
Procedure/Surgery

Primary outcome measure
Level of certainty in determining the primary origin of the tumor by 4 pathologists. Pathologists assess the macroscopic photos of each specimen and score how certain they are of the primary origin of the tumor (0-100%) in a survey.

Secondary outcome measures
1) Inter-observer agreement (kappa) among different pathologists in origin of the tumor (by survey)
2) R1 rate for pancreatic and periampullary cancers/lymph node harvest
Both determined during routine pathological examination.

Overall study start date
06/02/2018

Completion date
01/12/2019

Eligibility

Key inclusion criteria
1. All patients that undergo pancreatoduodenectomy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
128, 64 in each arm

Total final enrolment
128

Key exclusion criteria
1. Pancreatoduodenectomy performed for chronic pancreatitis
2. Pancreatoduodenectomy preoperatively confirmed neuro-endocrine tumors and hamoudi / acinar cell tumors
3. Pancreatoduodenectomy performed for tumors outside the periampullary region

Date of first enrolment
01/08/2018

Date of final enrolment
04/11/2019

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC, location AMC
Meibergdreef 9

Amsterdam
Netherlands
1105AZ

Study participating centre
Antonius Hospital
Koekoekslaan 1
Nieuwegein
Netherlands
3435CM

Study participating centre
Erasmus MC
Doctor Molewaterplein 40
Rotterdam
Netherlands
3015GD

Study participating centre
Radboud UMC
Geert Grooteplein Zuid 10
Nijmegen
Netherlands
6562GA

Sponsor information

Organisation
Amsterdam UMC, location AMC

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.amsterdamumc.nl

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		30/04/2019	23/05/2019	No	Yes
Results article		21/01/2021	13/08/2021	Yes	No
Protocol file		28/08/2019	05/10/2022	No	No