

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

Submission date 25/04/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Stijn van Roessel
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

- 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.

Completion date

01/12/2019

Eligibility

Key inclusion criteria

1. All patients that undergo pancreatoduodenectomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR
<https://ror.org/00q6h8f30>

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Results article		21/01/2021	13/08/2021	Yes	No
Participant information sheet		30/04/2019	23/05/2019	No	Yes

[Protocol file](#)

28/08/2019

05/10/2022

No

No