Comparison of 3.0T and 1.5T MRCP for the evaluation of pancreatic cysts

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27590

Source
NTR

Brief title
COMPACT

Health condition

Pancreatic cysts
Pancreascysten

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Investigator initiated

Intervention

Outcome measures

Primary outcome

Primary endpoint is the number of patients in whom a connection between the pancreatic cyst and PD can be visualized with increased certainty on 3.0T compared with 1.5T MRI/MRCP, evaluated by an experienced radiologist using a 5-point scale:

1: no connection PD

2: unlikely connection PD

3: undetermined connection PD

4: likely connection PD

5: clear connection PD

Secondary outcome

1. Change in follow-up or treatment strategy according to the current guidelines (International Association of Pancreatology (IAP) and European Cystic Tumor Study Group.

2. Visualization of worrisome features with 3.0T compared with 1.5T MRI/MRCP:

- Mural nodules

- Thickened/enhancing cyst walls

3. Difference in cyst morphology on 3.0T compared with 1.5T MRI/MRCP:

- Lobulation

- Pleomorphism

4. Amount of artefacts, evaluated by using a 3-point scale:
- 1: artefacts causing difficulties evaluating images

- 2: minor/moderate artefacts without diagnostic relevance

- 3: (almost) no artefacts

5. Interobserver agreement: intraclass correlation coefficient (ICC) values higher than 0.8 are considered to be excellent concordance, values between 0.6 and 0.8 as good, values between 0.4 and 0.6 as moderate, values between 0.2 and 0.4 as fair and values below 0.2 as poor

Study description

Background summary

Rationale: Distinction between the different types of pancreatic cysts is crucial, since some

cysts are benign without need for follow-up, whereas others are premalignant and require either surgical resection or surveillance. A key feature of the most common premalignant cyst, the side branch-intraductal papillary mucinous neoplasm (SB-IPMN), is the presence of a connection between the cyst and the pancreatic duct (PD). Current imaging, mostly done with 1.5T MRI/MRCP, is often not capable of visualizing this connection. Recent, small studies have suggested that 3.0T MRI/MRCP can provide superior image quality with improved delineation of the PD, but prospective studies in patients with pancreatic cysts are lacking. We hypothesize that 3.0T MRI/MRCP might be more accurate in visualizing a connection between a pancreatic cyst and the PD than 1.5T MRI/MRCP.

Objective: Primary objective is to compare the diagnostic ability of 3.0T and 1.5T MRI/MRCP in visualizing PD communication of pancreatic cysts. Second objectives are to compare the presence of mural nodules and thickened cyst wall and the amount of artefacts.

Study design: Prospective consecutive cohort of 20 patients.

Study population: Consecutive adult patients of the multidisciplinary pancreatic cyst clinic who are under follow-up for at least one pancreatic cyst in which no clear or likely connection with the PD has been seen on previous 1.5T MRI/MRCP and without classic features of a serous/mucinous cystic neoplasm.

Intervention: 3.0T MRI/MRCP during routine follow up of pancreatic cysts

Main study parameters/endpoints: Primary endpoint is the number of patients in whom a connection between the pancreatic cyst and PD can be visualized with 3.0T, whereas 1.5T MRI/MRCP could not.

Study objective

We hypothesize that 3.0T MRI/MRCP might be more accurate in visualizing a connection between a pancreatic cyst and the PD than 1.5T MRI/MRCP.

Study design

One 3.0T MRI/MRCP will be made during routine follow-up.

Intervention

Patients who are planned to undergo surveillance with MRI/MRCP will undergo 3.0T MRI/MRCP with contrast (gadovist) instead of 1.5T MRI/MRCP with gadovist. Imaging features of 3.0T MRI/MRCP and previously made 1.5T MRI/MRCP will be compared.

Contacts

Public
Dept. of Gastroenterology and Hepatology
Academic Medical Center
Meibergdreef 9, C2-310
S. Lekkerkerker
Amsterdam 1105 AZ
The Netherlands
+31-205662061
Scientific
Dept. of Gastroenterology and Hepatology
Academic Medical Center
Meibergdreef 9, C2-310
S. Lekkerkerker
Amsterdam 1105 AZ
The Netherlands
+31-205662061

Eligibility criteria

Inclusion criteria

- Patients with one or more pancreatic cysts (≥ 1 cm)

- ≥ 18 years old

- Previous 1.5T MRI/MRCP within 2 years of inclusion

- Written informed consent

Exclusion criteria

- Clear or likely connection between the cyst and the PD on previous 1.5T MRI/MRCP

- Clear imaging, biochemical and/or cytological features of serous/mucinous cystic neoplasms (i.e. honeycomb-like cyst, central scar, large unilocular cyst or Carcinoembryonic antigen (CEA) < 5).

- Medical history of chronic pancreatitis

- Any contraindication for MRI according to local guidelines

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-09-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5340
NTR-old	NTR5449
Other	METC AMC : W14_306 # 15.0264

Study results