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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27590

Bron
NTR

Verkorte titel
COMPACT

Aandoening

Pancreatic cysts
Pancreascysten

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Investigator initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-09-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten