Forward viewing US endoscope versus standard oblique viewing US endoscope in transmural drainage of pancreatic fluid collections: A randomized controlled trial.

Gepubliceerd: 02-12-2008 Laatst bijgewerkt: 18-08-2022

Objective: To compare endoscopic pancreatic fluid collection drainage using a standard oblique-viewing US endoscope versus a prototype forward viewing ultrasonic endoscope with emphasis on ease of endoscopic drainage measured by procedural time.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24857

Bron
NTR

Verkorte titel
Forward vs Oblique EUS

Aandoening

Pancreatic Fluid Collections

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam
Overige ondersteuning: Academic Medical Center, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint will be ease of endoscopic drainage measured by procedural time.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Transmural endoscopic drainage has become treatment of first choice for uncomplicated pancreatic fluid collections.
Drainage is mostly performed with presently available therapeutic oblique-viewing (45°) ultrasonic endoscopes.
Puncturing under an angle sometimes hampers successful completion of the procedure because the force that is applied while introducing instruments through the working channel is not fully exerted at the tip of the accessory, but instead drives the endoscope away from the gut wall. A prototype forward viewing ultrasonic endoscope was developed to overcome this difficulty.

Objective:
To compare endoscopic pancreatic fluid collection drainage using a standard oblique-viewing US endoscope versus a prototype forward viewing ultrasonic endoscope with emphasis on ease of endoscopic drainage measured by procedural time.

Study design:
A multicenter randomised controlled, clinical trial.

Study population:
Patients with pancreatic fluid collections in which endoscopic drainage is indicated.

Intervention:
Patients will be randomly assigned to receive either endoscopic drainage with a forward viewing or standard oblique viewing ultrasonic endoscope.

Primary study parameter:
The primary endpoint will be ease of endoscopic drainage measured by procedural time.

Secondary study parameters:
Successful drainage procedures, resolution of pancreatic fluid collections, procedure related complications, US endoscope preference according to post-procedural questionnaire.

Doel van het onderzoek

Objective: To compare endoscopic pancreatic fluid collection drainage using a standard oblique-viewing US endoscope versus a prototype forward viewing ultrasonic endoscope with emphasis on ease of endoscopic drainage measured by procedural time.

Onderzoeksopzet

Data are collected by principal investigator or research nurse via a case record form. Patients are observed during their hospital stay. Patients will be followed for a period of 12 months. During this follow up patients will be seen twice on the outpatient clinic (12 weeks and 52 weeks). Abdominal imaging will be performed 10 weeks after last endoscopic drainage procedure. If there is total resolution of the collection is, the stents will be removed.

In case of recurrence of the fluid collection after stent removal or a dilated pancreatic duct (> 5mm) an endoscopic retrograde pancreatogram (ERP) is performed to evaluate the pancreatic duct. If a stricture or fistula is visualized, stenting of the pancreatic duct will be attempted. Follow-up MRI abdominal imaging will be performed 3 months after stent removal.

Onderzoeksproduct en/of interventie

Patients will be randomly assigned to receive either endoscopic drainage with a forward viewing or standard oblique viewing ultrasonic endoscope.

Contactpersonen

Publiek

Academic Medical Center (AMC)
Department of Gastroenterology
P.O. Box 22660
P. Fockens
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Wetenschappelijk

Academic Medical Center (AMC)
Department of Gastroenterology
P.O. Box 22660
P. Fockens
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Presence of a large (> 6 cm) pancreatic fluid collection.

2. Window for endoscopic drainage.

3. Age > 17 years.

4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous surgical or endoscopic drainage.

2. Participation in another intervention trial that would interfere with the intervention and outcome of this study.

3. Transduodenal as the preferred route.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-01-2008
Aantal proefpersonen:	52
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-12-2008
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	NL1502
NTR-old	NTR1572
Ander register	: MEC 08/076
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A