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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24857

Source
NTR

Brief title
Forward vs Oblique EUS

Health condition

Pancreatic Fluid Collections

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

Study description

Background summary

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.

Study objective

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

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.

Intervention

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

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Eligibility criteria

Inclusion criteria

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

2. Window for endoscopic drainage.

3. Age > 17 years.

4. Written informed consent.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-01-2008
Enrollment:	52
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-12-2008
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	NL1502
NTR-old	NTR1572
Other	: MEC 08/076
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A