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

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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.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON32157

Source
ToetsingOnline

Brief title
Forward vs oblique viewing US endoscope

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
Symptomatic pancreatic fluid collections

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pseudocyst, Ultrasonic endoscopy

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

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.

Study 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

Intervention

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

Study burden and risks

Because endoscopic drainage will be indicated in all patients, the extra burden will be limited. There will be a small chance that endoscopic drainage is not successful with the prototype forward viewing US endoscope. Consequently, the procedure need to be repeated with a standard oblique viewing endoscope. On the other hand, it may happen that a pancreatic fluid collection can be drained with the forward viewing and NOT with the standard oblique viewing, and participating in this study may appear to be beneficial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Presence of a large (> 6 cm) pancreatic fluid collection.
* Window for endoscopic drainage
* Age > 17 years
* Written informed consent

Exclusion criteria

* Previous surgical or endoscopic drainage
* Participation in another intervention trial that would interfere with the intervention and outcome of this study.
* Transduodenal as the preferred route

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008

Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL22387.018.08