

A prospective randomised trial comparing EUS guided and conventional endoscopic pseudocyst drainage.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24809

Source

NTR

Brief title

DEUS

Health condition

Pancreatic pseudocysts.

Sponsors and support

Primary sponsor: N/A

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Technical success rate (cyst resolution).

Secondary outcome

1. Clinical success rate (symptom relief);
2. Complication rate;
3. Recurrence rate.

Study description

Background summary

N/A

Study objective

To compare Endoscopic ultrasound (EUS) guided pseudocyst drainage to conventional non-EUS guided endoscopic drainage.

Study design

N/A

Intervention

1. Endoscopic pseudocyst drainage under direct EUS vision executed by a therapeutic radial echoendoscope;
2. Conventional endoscopic pseudocyst drainage using a therapeutic duodenoscope preceded by a diagnostic EUS procedure.

Contacts

Public

Academic Medical Center (AMC),
P.O. Box 22660

Djuna Cahen
Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 3474723

Scientific

Academic Medical Center (AMC),
P.O. Box 22660

Djuna Cahen
Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 3474723

Eligibility criteria

Inclusion criteria

1. Pseudocyst > 5 cm in size;
2. Presence > 6 weeks.

Exclusion criteria

1. Pregnancy;
2. ASA klass III/IV;
3. Haemorrhagic diathesis;
4. Decompensated liver cirrhosis;
5. Dilated pancreatic duct > 5 mm;
6. Suspected malignancy;
7. Distance between cyst - gut lumen > 1 cm;
8. Multiple septae (indication for surgery).

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2001
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion	
Date:	12-09-2005
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	NL484

Register

NTR-old

Other

ISRCTN

ID

NTR527

: N/A

Incomplete data for ISRCTN

Study results

Summary results

N/A