Timing of removal of transluminal stents after endoscopic drainage of pancreatic fluid collections: A randomized controlled multicenter trial.

No registrations found.

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

Summary

ID

NL-OMON26002

Source
Nationaal Trial Register

Brief title
REMOVE

Health condition

acute pancreatitis
pancreatic fluid collection
double pigtail stent
plastic stent
endoscopic transmural drainage
abnormal pancreatic duct
pancreatic fluid collection recurrence

Sponsors and support

Primary sponsor: University Medical Center
Source(s) of monetary or material Support: No funding

Intervention

Outcome measures

Primary outcome

Recurrence of a PFC (>6 cm or symptomatic) proximal to the initial PD disruption after an endoscopically drained PFC at or within 18 months after randomization.

Secondary outcome

1. Complications caused by spontaneous stent migration into the cyst;

2. Number of spontaneous stent migrations before removal.

Study description

Background summary

Rationale:

An acute pancreatitis can be complicated by a pancreatic fluid collection (PFC) which can be treated by endoscopic drainage with transluminal stent placement. In case of pancreatic duct (PD) disruption, it may be favorable, as for recurrence of the PFC, to leave the transluminal stents in situ at least during the first year following endoscopic drainage.

Objective:

The aim of this study is to compare recurrence rate of a PFC in patients with a PD disruption in which transluminal stents after endoscopic drainage and resolution of PFC are either removed early within 2 weeks of randomization (12-16 weeks after drainage) or 12 months after randomization (15 months after drainage).

Study design:

Randomized controlled multicenter trial.

Study population:

All consecutive patients over 18 years with an abnormal PD on S-MRCP that are being treated for a PFC by endoscopic drainage with transluminal stents.

Intervention:

Following transluminal endoscopic drainage, an S-MRCP will be made. Patients with an abnormal PD will be randomized to either stent removal within 2 weeks of randomization or stent removal at 12 months after randomization.

Main study parameters/endpoints:

Recurrence of a PFC (>6 cm or symptomatic) proximal to the initial PD disruption after endoscopic drainage at or within 18 months after randomization.

Study objective

An acute pancreatitis can be complicated by a pancreatic fluid collection (PFC) which can be treated by endoscopic drainage with transluminal stent placement. In case of pancreatic duct (PD) disruption, it may be favorable, as for recurrence of the PFC, to leave the transluminal stents in situ at least during the first year following endoscopic drainage.

The aim of this study is to compare recurrence rate of a PFC in patients with a PD disruption in which transluminal stents after endoscopic drainage and resolution of PFC are either removed early within 2 weeks of randomization (12-16 weeks after drainage) or 12 months after randomization (15 months after drainage).

Study design: Randomized controlled multicenter trial.

Study design

Study patients will be followed for 18 months.

Intervention

Group A:

1. Endoscopic stent removal within 2 weeks of randomization;

2. Follow-up S-MRCP at T=6 months, T= 12 months, T= 18 months.

Group B:

1. Endoscopic stent removal within 2 weeks of 12 month S-MRCP;

2. Follow-up S-MRCP at T=6 months, T=12 months, T=18 months.

Contacts

Public
Dept. of Gastroenterology and Hepatology/ Dept. of Surgery
Academic Medical Center Amsterdam
Meibergdreef 9
Tessa Verlaan
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5665584
Scientific
Dept. of Gastroenterology and Hepatology/ Dept. of Surgery
Academic Medical Center Amsterdam
Meibergdreef 9
Tessa Verlaan
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5665584

Eligibility criteria

Inclusion criteria

1. Patient over 18 years old;

2. PFC resolution (no remaining fluid collection larger than 3 cm);

3. Pigtail(s) positioned in remnant PFC;

4. Abnormal PD on S-MRCP performed 12-16 weeks after drainage;

5. Ductal dilation (≥ 5 mm in body or tail);

6. Ductal disruption;

7. Both ductal dilation and ductal disruption.

Exclusion criteria

1. PFC complicating chronic pancreatitis;

2. PFC after surgery;

3. Recurrence of prior treated PFC;

4. Acute-on-chronic pancreatitis.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-05-2012
Enrollment:	68
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-01-2013
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	NL3625
NTR-old	NTR3791
Other	: 35810
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A