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

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To evaluate the hypothesis that patients with an abnormal pancreatic duct (PD) in which the transluminal stents are left in situ have a lower pancreatic fluid collection recurrence rate after endoscopic transluminal drainage in comparison to...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal conditions NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON39383

**Source**
ToetsingOnline

**Brief title**
REMOVE

### Condition

- Gastrointestinal conditions NEC

**Synonym**
Pancreatic pseudocyst

**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, remove, stent

## Outcome measures

### Primary outcome

Recurrence of a PFC (>6 cm or symptomatic) proximal to the initial PD

disruption after endoscopic drainage at or within 18 months after initial

drainage

### Secondary outcome

* Complications such as infection, pain that could be associated to leaving

stents in situ

* Number of spontaneous stent migrations before removal

# Study description

### Background summary

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

### Study objective

To evaluate the hypothesis that patients with an abnormal pancreatic duct (PD) in which the transluminal stents are left in situ have a lower pancreatic fluid collection recurrence rate after endoscopic transluminal drainage in comparison to patients in which the transluminal stents are retrieved.

### Study design

Randomized controlled multi-center trial

**Study burden and risks**

For this study we will evaluate the hypothesis that patients with an abnormal pancreatic duct in which the transluminal stents are left in situ have a lower pancreatic fluid collection recurrence rate after endoscopic transluminal drainage in comparison to patients in which the transluminal stents are retrieved. Benefits of leaving the stents in situ for a longer period of time could be a lower recurrence rate of a pancreatic fluid collection. Associated risks could be infection and pain that can be associated with leaving the stents in situ. Additionally, the stents can migrate spontaneously. In case of complications the gastroenterologist will decide to reintervene endoscopically and if necessary decide to remove the stents prematurely.

# Contacts

**Public**
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
**Scientific**
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

### Inclusion criteria

* Patient over 18 years old
* PFC resolution (no remaining fluid collection larger than 3 cm)
* Pigtail(s) positioned in remnant PFC
* Abnormal PD on S-MRCP performed 12-16 weeks after drainage
- ductal dilation (* 5 mm in body or tail)
- ductal disruption
- both ductal dilation and ductal disruption

### Exclusion criteria

* PFC complicating chronic pancreatitis
* PFC after surgery
* Recurrence of prior treated PFC
* Acute-on-chronic pancreatitis

## Study design

### Design

**Study type:** Observational invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 24-08-2013 |
| Enrollment: | 55 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 21-05-2012 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-06-2013 |
| Application type: | Amendment |
| 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 | NL35810.018.12 |