Transluminal drainage of pancreatic fluid collections using a self-expandable metallic stent.

No registrations found.

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

Summary

ID

NL-OMON23102

Source
Nationaal Trial Register

Brief title
PATENT

Health condition

acute pancreatitis
systematic pancreatic fluid collection
endoscopic transmural drainage
self-expandable metal stent

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The primary endpoints are safety and efficacy:

1. Safety is expressed as the number of SAEs that are related to the procedure;

2. Efficacy is expressed as the number of PFC resolutions at 3 months after drainage.

The intervention is considered safe when the maximum rate of SAE's (related to the treatment) is 5%.

The procedure is regarded effective if at least 85% of PFC have been resolved at 3 months. PFC resolution is defined as a PFC < 3 cm.

Secondary outcome

1. 'Ease of use' measured as the scope-in and scope-out time interval during the procedure in which the SEMS is placed;

2. Removability of covered self-expendable metallic stent after PFC resolution.

Removability and ease of use will be graded on a visual analogue scale of 0-10: 0 being not able to remove the SEMS and 10 very easy removal of the SEMS.

Study description

Background summary

Acute or chronic pancreatitis may be complicated by a (peri)pancreatic fluid collection (PFC) which can be treated by endoscopic drainage with transluminal stent placement. The efficacy of transluminal drainage of pancreatic fluid collections may be increased by creation of a larger fistula than currently possible with placement of multiple plastic endoprostheses.

Objective:

To evaluate the safety and efficacy of using a covered self-expandable metallic stent (SEMS) for transluminal endoscopic drainage of a pancreatic fluid collection.

Study design:

Prospective cohort (pilot) study with 25 patients.

Study population:

All consecutive patients over 17 years with a symptomatic pancreatic fluid collection.

Intervention:

Placement of a covered self-expandable metallic stent for transluminal drainage of a pancreatic fluid collection.

Main study parameters/endpoints:

The primary endpoints are safety and efficacy.

Study objective

The efficacy of transluminal drainage of pancreatic fluid collections may be increased by creation of a larger fistula than currently possible with placement of multiple plastic endoprostheses.

Study design

Total study duration is 6 months.

Intervention

Endoscopic transmural drainage of pancreatic fluid collecting with placement of self-expandable metal stent.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient over 17 years;

2. Symptomatic pancreatic fluid collection that requires endoscopic drainage.

Exclusion criteria

1. Infected pancreatic necrosis;

2. Recurrence of prior treated pancreatic fluid collection;

3. Not fulfilling standard criteria to undergo PFC drainage according to local guidelines;

4. ASA class IV or V.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2013
Enrollment:	25
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	NL3641
NTR-old	NTR3793
Other	ABR : 40756
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A