

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

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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 endoprotheses.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23102

Bron

Nationaal Trial Register

Verkorte titel

PATENT

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center

Overige ondersteuning: No funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 endoprotheses.

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.

Doel van het onderzoek

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 endoprotheses.

Onderzoeksopzet

Total study duration is 6 months.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient over 17 years;
2. Symptomatic pancreatic fluid collection that requires endoscopic drainage.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart

(Verwachte) startdatum: 01-02-2013
Aantal proefpersonen: 25
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 14-01-2013
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3641
NTR-old	NTR3793
Ander register	ABR : 40756
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A