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

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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...

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

Samenvatting

ID

NL-OMON26002

Bron
Nationaal Trial Register

Verkorte titel
REMOVE

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center
Overige ondersteuning: No funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Study patients will be followed for 18 months.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. PFC complicating chronic pancreatitis;

2. PFC after surgery;

3. Recurrence of prior treated PFC;

4. Acute-on-chronic pancreatitis.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-05-2012
Aantal proefpersonen:	68
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	NL3625
NTR-old	NTR3791
Ander register	: 35810
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A