Early Surgery versus optimal Current step-up prActice for chronic PancrEatitis.

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We hypothesis that early surgical intervention results in less pain over the study period and is more cost-effective than the optimal current step-up practice.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27341

Bron
NTR

Verkorte titel
ESCAPE

Aandoening

Chronic pancreatitis

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
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Overige ondersteuning: 1. Dutch Digestive Diseases Foundation (The Netherlands) - (Grant nr. WO10-21)

2. ZonMw Health Care Efficiency Research Program (The Netherlands) - (Grant nr. 171102016)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary clinical outcome is the degree of pain as assessed by the Izbicki pain score at 2 weeks intervals during the follow-up period of 18 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

In current clinical practice, surgical intervention for chronic pancreatitis (CP) is primarily kept as a last resort after medical and endoscopic management has failed and disease severity has become unbearable. Recent evidence suggests that earlier surgical intervention benefits patients in terms of better pain control and preservation of pancreatic function.

Objective:

Evaluate the benefits, risks and costs of early surgical intervention as an alternative to current step-up practice for CP.

Study design:

A multi-center strategy randomized controlled trial.

Study population:

Patients with confirmed CP and dilated pancreatic duct (≥ 5mm) with moderate pain (pain relieved without opioids) will be registered and followed monthly as potential candidates for the trial. When a registered patient meets the randomization criteria (need for opioid analgesics) the patient will be randomized to one of the intervention arms. An Expert Panel of CP specialists will oversee the assessment of eligibility and ensure that allocation to either treatment arm is possible.

Intervention:

Patients will be randomly allocated to either:

1. Early surgical intervention;

2. Optimal current step-up practice.

They will receive the following interventions:

Group 1: Early surgical intervention:

Surgical drainage of the pancreatic duct (pancreaticojejunostomy) if pancreatic head is not enlarged (< 4 cm); or surgical drainage of the pancreatic duct and resection of the head of the pancreas (Frey procedure) if pancreatic head is enlarged (≥ 4cm);

Group 2: Optimal current step-up practice:

Step 1: Optimal medical management, if not effective followed by;

Step 2: Endoscopic intervention, and if not effective followed by;

Step 3: Surgical intervention.

Main study parameters/endpoints:

Primary outcome is pain assessed with the Izbicki pain score. Secondary outcomes are severe complications, mortality, cost-effectiveness, quality of life, pancreatic insufficiency, alternative pain scales, hospital admissions and number of performed interventions.

Doel van het onderzoek

We hypothesis that early surgical intervention results in less pain over the study period and is more cost-effective than the optimal current step-up practice.

Onderzoeksopzet

The patient follow-up will be completed 18 months after randomization for the primary endpoint, the secondary endpoints and the other research questions.

Onderzoeksproduct en/of interventie

Intervention group:

Early surgical intervention: Surgical drainage of the pancreatic duct (pancreaticojejunostomy) if pancreatic head is not enlarged (< 4 cm); or surgical drainage of the pancreatic duct and resection of the head of the pancreas (Frey procedure) if pancreatic head is enlarged (4cm).

Control group:

Optimal current step-up practice:

Step 1: Optimal medical management, if not effective followed by;

Step 2: Endoscopic intervention, and if not effective followed by;

Step 3: Surgical intervention.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Registration criteria:

1. Age 18 years;

2. Confirmed chronic pancreatitis: according to the M-ANNHEIM diagnostic criteria;

3. Dilated pancreatic duct (5 mm, established by MRCP, CT or EUS), with or without enlargement of the pancreatic head;

4. Presence of moderate, non-debilitating pain. This will be defined as chronic abdominal pain (present for at least 3 months) sufficiently relieved with non-opioid analgesics.

Randomization criteria (after fulfilling inclusion criteria for registration):

1. Need for upgrade from non-opioids to opioid analgesics: newly developed need for opioids analgesics (opioids needed at least 3 days per week) and persistently needed for at least 2 weeks in a row;

2. Informed consent for randomization.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of prolonged need of opioids for chronic pancreatitis for a period over 2 months in the last 2 years;

2. Previous pancreatic surgery;

3. Previous endoscopic dilatation or stenting of the pancreatic duct;

4. Episode of biliary obstruction in the last 2 months (defined as jaundice or bilirubine levels 25 micromol / L) or the presence of a stent in the common bile duct (CBD);

5. Proven autoimmune pancreatitis (including elevated levels of gamma-globulins (IgG));

6. Suspected or established pancreatic malignancies;

7. Life expectancy of < 1 year for any reason;

8. Presence of duodenal obstruction necessitating surgery, as judged by the expert panel;

9. Presence of a pseudocyst larger than 6 cm necessitating intervention, as judged by the expert panel;

10. Contra-indications for surgery, always evaluated by the expert panel (e.g. American Society of Anesthesiology class IV, severe portal hypertension due to occluded portal vein);

11. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	88
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL2666
NTR-old	NTR2794
Ander register	ZonMw / MLDS : 171102016/ WO10-21;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A