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

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

Ethical review	-
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON38261

Source
ToetsingOnline

Brief title
ESCAPE

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
chronic pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Endoscopic, Medical, Pancreatitis, Surgery

Outcome measures

Primary outcome

Primary outcome is pain assessed with the Izbicki pain score.

Secondary outcome

Secondary outcomes are severe complications, mortality, cost-effectiveness,

quality of life, pancreatic insufficiency, alternative pain scales, hospital

admissions and number of performed interventions.

Study description

Background summary

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.

Study 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

Intervention

Patients will be randomly allocated to either A) early surgical intervention or B) optimal current step-up practice and will receive the following interventions:

Group A. 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 B. 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.

Study burden and risks

In group A (early surgery) the risks are that of surgery. There may be complications such as infection, bleeding into the abdominal cavity or damage to the intestine. Sometimes these complications may prolong the hospital stay or sometimes a second operation is needed.

In group B (optimal current step-up practice) the medication can cause constipation, itching, drowsiness and may cause addiction when used for a long period of time. At endoscopy, there are risks of damage to the intestine, pancreas or bile ducts. This can lead to a longer hospital stay or a second operation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age * 18 years
2. Confirmed chronic pancreatitis: according to the following criteria (adapted from the M-ANNHEIM diagnostic criteria):
* typical clinical history of chronic pancreatitis (i.e. recurrent pancreatitis or abdominal pain), and:
* one or more of the following additional criteria for the diagnosis of chronic pancreatitis:
a. Pancreatic calcifications
b. Moderate or marked ductal lesions (according to the Cambridge classification) on magnetic resonance cholangiopancreatography (MRCP), computed tomography (CT) or endoscopic ultrasounds (EUS) imaging
c. Marked and persistent exocrine insufficiency (defined as: a. pancreatic steatorrhea clearly relieved by enzyme supplementation, and/or b. fecal elastase levels of * 200 micro gram/gram)
3. Dilated pancreatic duct: dilated pancreatic duct of * 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 or recurrent abdominal pain sufficiently relieved with non-opioid analgesics;Patients will be eligible for randomization to one of the trial arms when the randomization criteria are met:
* In patients with chronic abdominal pain related to chronic pancreatitis: a need to upgrade pain medication from non-opioids to opioid analgesics (opioids needed at least 3 days per week) and persistently needed for at least 2 weeks in a row
* In patients with recurrent flare ups of chronic pancreatitis (including episodes of acute on chronic pancreatitis) and pain-free intervals that:
- have occurred at least 3 times during one year (i.e. 12 months);
- during at least 7 consecutive days;
- necessitate opioid use during flare up;
- impairs the patient in daily activities.
* Informed consent for randomization

Exclusion criteria

* History of prolonged need of opioids: history for need for strong opioids for CP for a total period over 2 months or a history for need for weak opioids for CP for a total period of 6 months in the last 2 years
* Previous pancreatic surgery
* Previous endoscopic dilatation or stenting of the pancreatic duct. Patients with previous endoscopic intervention for biliary obstruction, without intervention involving the pancreatic duct, will be eligible for the trial.
* 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).
* Proven autoimmune pancreatitis (including elevated levels of gamma-globulins (IgG))
* Stones and strictures exclusively located in the tail of the pancreas (defined as to the left of the left border of the vertebra) with relatively normal pancreatic head and corpus.
* Fully impacted stones casting the entire main pancreatic duct (from head to tail) and side branches.
* Suspected or established pancreatic malignancies
* Life expectancy of < 1 year for any reason
* Presence of duodenal obstruction necessitating surgery, as judged by the expert panel
* Presence of a pseudocyst larger than 6 cm necessitating intervention, as judged by the expert panel
* 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)
* Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	27-04-2011
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-09-2012
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
ISRCTN	ISRCTN45877994
CCMO	NL34701.018.10