

# Endoscopic versus surgical drainage of the pancreatic duct in chronic pancreatitis; a prospective randomised trial.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27733

### Source

NTR

### Brief title

CEPAN

### Health condition

Chronic pancreatitis (CP).

## Sponsors and support

**Primary sponsor:** N/A

**Source(s) of monetary or material Support:** N/A

## Intervention

## Outcome measures

### Primary outcome

Mean Izbicki painscore during follow-up.

## Secondary outcome

1. Clinical success: pain relief at end of FU;
2. Complete (Izbicki pain score  $\leq 10$ );
3. Partial ( $>50\%$  decrease, total score  $> 10$ );
4. Morbidity and mortality rate;
5. Intervention rate;
6. Hospital stay;
7. Development of endo- and/or exocrine pancreatic insufficiency.

## Study description

### Background summary

N/A

### Study objective

N/A

### Study design

N/A

### Intervention

1. Surgical drainage: pancreaticojejunostomy;
2. Endoscopic drainage: ESWL and/or pancreatic stenting.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

1. A diagnosis of CP, based on clinical symptoms in combination with morphological changes established by imaging studies (calcifications or ductal changes) and/or pancreatic functional insufficiency;
2. A dominant obstruction of the Pancreatic Duct, demonstrated by presence of a stenosis and/or intraductal stones on MRCP and abdominal CT-scan, located left from the spine, with pre-stenotic ductal dilatation of at least 5 mm;
3. Severe recurrent pancreatic pain with insufficient relieve by non-narcotic analgesics or requiring opiates.

### Exclusion criteria

1. Age below 18 or over 80 years;
2. Pancreatic head enlargement > 4 cm;
3. Contra-indication for surgery; ASA class 4, severe portal hypertension;

4. Contra-indications for endoscopy: gastrectomy with Billroth II reconstruction, other pancreatitis related complications (bile duct stricture, pseudocyst) requiring surgery;
5. Previous pancreatic surgery;
6. Suspected pancreatic malignancy;
7. Limited life expectancy (< 2 years);
8. Pregnancy.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2000
Enrollment:	39
Type:	Actual

## Ethics review

Positive opinion	
Date:	09-09-2005
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	NL188
NTR-old	NTR225
Other	: N/A
ISRCTN	ISRCTN04572410

## Study results

### Summary results

1. Ned Tijdschr Geneeskd. 2007 Nov 24;151(47):2624-30.; <br><br>
2. N Engl J Med. 2007 Feb 15;356(7):676-84.<br>