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Endoscopic versus surgical drainage of the pancreatic duct in chronic pancreatitis: a prospective randomised trial

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 17/09/2008	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
CEPAN

Study objectives
To compare endoscopic and surgical drainage of the pancreatic duct.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic pancreatitis (CP)

Interventions
1. Surgical drainage: pancreaticojejunostomy
2. Endoscopic drainage: extracorporeal shock wave lithotripsy (ESWL) and/or pancreatic stenting

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Mean Izbicki pain score during follow-up

Secondary outcome measures
Clinical success:
1. Pain relief at end of FU
2. Complete (Izbicki pain score less than or equal to 10)
3. Partial (greater than 50% decrease, total score greater than 10)
4. Morbidity and mortality rate
5. Intervention rate
6. Hospital stay
7. Development of endo- and/or exocrine pancreatic insufficiency

Overall study start date
01/01/2000

Completion date
01/10/2004

Eligibility

Key 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 magnetic resonance cholangiopancreatography (MRCP) and abdominal computed tomography (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

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
39

Key exclusion criteria
1. Age below 18 or over 80 years
2. Pancreatic head enlargement greater than 4 cm
3. Contra-indication for surgery; American Society of Anaesthesiologists (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 (less than 2 years)
8. Pregnancy

Date of first enrolment
01/01/2000

Date of final enrolment
01/10/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Meibergdreef 9
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Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type

Industry

Funder Name
AstraZeneca (The Netherlands) - unrestricted grant

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	15/02/2007		Yes	No