

Prospective, randomised, single-blind study for validation of the effect of endoscopic stent implantation and drainage on patients with chronic pancreatitis and pancreas duct stenosis

Submission date 20/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/09/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

PAGASTE

Study objectives

The background is the already aged obstruction hypothesis. It is assumed that a relevant stricture of the pancreatic duct leads to retention and stasis of the pancreatic juice thereby mitigating pain and inflammation. If the stent achieves a drainage the frequency of episodes of pain and inflammation should be significantly reduced.

Please note that as of 08/09/09 the contact address and ethics approval have been updated. Please also note that the end date of this trial has been extended from 01/04/07 to 31/12/2010.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 08/09/09: Received from Leipzig Medical Faculty ethics committee, University of Leipzig on the 14th of April 2004

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic pancreatitis with pancreatic duct stenosis

Interventions

Endoscopic stenting of the pancreatic duct, stent exchange after 3 months versus conservative treatment with analgesics

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Total pain score during first 3 month after ERCP, specialised Pancreas Pain Questionnaire checked for reliability and validity

Secondary outcome measures

1. Use of analgesics
2. Frequency of pain episodes within one year
3. Treatment failure
4. Signs of endocrine/exocrine failure
5. Change of diameter of pancreatic duct during treatment

Overall study start date

01/05/2004

Completion date

31/12/2010

Eligibility**Key inclusion criteria**

1. Chronic pancreatitis with evidence of magnetic resonance cholangiopancreatography (MRCP) or endoscopic retrograde cholangiopancreatography (ERCP)
pancreatic duct stricture (>50%) in pancreatic head
2. Chronic recurrent pain
3. Age >18, <75, WIC

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Radiation of upper abdominal or lower chest area
2. Uncured cancer or systemic chemotherapy within last 5 years
3. Failure of compliance
4. Foreseeable pregnancy
5. Participation in other therapeutic trials within last 30 days
6. Patients continuous free of symptoms

Date of first enrolment

01/05/2004

Date of final enrolment

31/12/2010

Locations**Countries of recruitment**

Germany

Study participating centre

Liebigstrasse 20

Leipzig

Germany

04103

Sponsor information**Organisation**

University of Leipzig (Germany)

Sponsor details

Liebigstrasse 20

Department of Surgery II

Leipzig

Germany

04103

Sponsor type

University/education

ROR

<https://ror.org/03s7gtk40>

Funder(s)

Funder type

University/education

Funder Name

University of Leipzig (Germany)

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