ISRCTN13044540 https://doi.org/10.1186/ISRCTN13044540

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

Registration date
21/10/2005

Overall study status
Completed

Last Edited
08/09/2009

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Total pain score during first 3 month after ERCP, specialised Pancreas Pain Questionaire checked for reliability and validity

Key secondary outcome(s))
1. Use af 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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/03s7gtk40

Funder(s)

Funder type
University/education

Funder Name
University of Leipzig (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration