

Comparison of duodenum-preserving pancreatic head resection after Frey and after Berner as treatment of chronic pancreatitis

Submission date 22/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/09/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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

Comparison of duodenum-preserving pancreatic head resection after Frey and after Berner as treatment of chronic pancreatitis

Acronym

Frey-Berner

Study objectives

Both surgical procedures are accepted as treatment for patients with chronic pancreatitis and chronic pain. They are both pancreatic tissue preserving in comparison to classic Whipple-procedure. The procedure after Berner is the shorter and less invasive surgical procedure with less resection of pancreatic tissue. Assuming an equal outcome in patients with chronic pancreatitis, the modification of Berner could be the gold standard as the least invasive and tissue resecting procedure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

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

Interventions

Two surgical procedures in comparison - duodenum-preserving pancreatic head resection after Berner and after Frey.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Quality of life

Secondary outcome measures

1. Local complications
2. Mortality
3. Morbidity
4. Exocrine and endocrine pancreatic function

Overall study start date

01/03/2005

Completion date

01/08/2007

Eligibility**Key inclusion criteria**

1. Chronic pancreatitis
2. Chronic pain greater than 1 year
3. Complications of chronic pancreatitis as duodenal stenosis or treatment resistant pancreatic duct stenosis

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

66 patients - 33/group

Key exclusion criteria

1. Chronic pancreatitis without involvement of pancreatic head
2. Hints for malignant pancreas disorders
3. Not cured cancer or chemotherapy or radiation within last 5 years

Date of first enrolment

01/03/2005

Date of final enrolment

01/08/2007

Locations

Countries of recruitment

Germany

Study participating centre

Department of Surgery, Clinic II

Leipzig

Germany

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Sponsor information

Organisation

University of Leipzig (Germany)

Sponsor details

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		16/04/2008	01/09/2021	No	No