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Clinical trial to compare duodenum preserving pancreatic head resection according to Beger versus the Berne modification in patients with chronic pancreatitis: a randomised controlled trial

Submission date 27/05/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 01/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 30/08/2011	**Condition category** Digestive System	[_] 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

Protocol serial number
KSC 06/2003

Study information

Scientific Title

Acronym
DEPKR-Trial

Study objectives
To compare two different surgical techniques for the treatment of chronic pancreatitis with regard to complication rates, length of operation, length of intensive care treatment, length of hospital stay, exocrine/endocrine pancreatic function and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Independent Ethics Committee of the University of Heidelberg.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Every patient eligible for pancreatic head resection due to chronic pancreatitis will be asked for informed consent and will be thereafter intraoperatively randomised to either Beger's or the Berne modification of duodenum-preserving pancreatic head resection. A standardised surgical abdominal approach is performed in preparing the pancreatic head. The randomisation will proceed when the intraoperative decision for resection of the pancreatic head is made. The comparison of specific primary and secondary endpoints will assess the superiority of one technique. Patients will be followed up for 24 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary endpoint is combined out of four components. In order to adjust for multiple testing a hierarchical model is used.

1. Duration of surgical procedure [min]
2. Quality of life (EORTC QLQ-C30 questionnaire and the disease specific module for pancreatic diseases EORTC QLQ-PAN26) at 12 months after the intervention
3. Duration of stay on the intensive care unit
4. Duration of postoperative hospital stay

Key secondary outcome(s))
Frequencies of early and late onset complications such as intra- or postoperative bleeding with subsequent need for blood transfusion, pancreatic fistula, postoperative pulmonary complications, wound infections and re-laparotomy; exocrine and endocrine pancreatic function as determined by levels of HbA1c and stool elastase.

Completion date
01/10/2007

Eligibility

Key inclusion criteria
Patients undergoing elective duodenum-preserving pancreatic head resection due to chronic pancreatitis.

Eligibility criteria:
1. Patients of any age (greater than 18 years)
2. Expected survival time more than 24 months
3. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Participation in another intervention trial that would interfere with the intervention and outcome of this study
2. Severe psychiatric disorders or neurological diseases
3. Lack of compliance
4. Drug and/or alcohol abuse according to local standards

Date of first enrolment
01/09/2003

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
Germany

Study participating centre
University of Heidelberg Medical School
Heidelberg
Germany
69120

Sponsor information

Organisation
University of Heidelberg Medical School (Germany)

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
University/education

Funder Name
University of Heidelberg Medical School (Germany)

Results and Publications

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	01/04/2008		Yes	No
Protocol article	Protocol	08/05/2006		Yes	No