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

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

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/09/2003

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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
65

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
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Germany
69120

Sponsor information

Organisation
University of Heidelberg Medical School (Germany)

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Sponsor type
University/education

Website
http://med.uni-hd.de/index_eng.html

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
University/education

Funder Name
University of Heidelberg Medical School (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?
Protocol article	Protocol	08/05/2006		Yes	No
Results article	Results	01/04/2008		Yes	No