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Duodenum-preserving head resection versus pancreatico-duodenectomy for chronic pancreatitis of the head

Submission date	Recruitment status	[X] Prospectively registered
21/04/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/08/2018	Digestive System	

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
SDGC 01/2009

Study information

Scientific Title
Duodenum-preserving head resection versus pancreatico-duodenectomy for chronic pancreatitis of the head: a randomised controlled multicentre trial

Acronym
ChroPac

Study objectives
The two-sided null-hypothesis states that both surgical interventions lead to the same average quality of life (QoL) scores during 24 months after surgery. The two-sided alternative-hypothesis states that the two interventions perform differently in terms of the primary efficacy endpoint.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Heidelberg, approved on 20/04/2009 (ref: S-029/2009)

Primary study design
Interventional

Study design
Prospective randomised controlled observer and patient blinded multicentre surgical trial with two parallel study groups

Study type(s)
Treatment

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

Interventions
Experimental intervention:
Any surgical technique that removes inflamed pancreatic tissue of the head without resection of the duodenum (e.g. Beger, Frey or Berne procedure).

Control intervention:
Pylorus preserving/classic Whipple procedure.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Average QoL during 24 months after surgery, measured 6, 12 and 24 months after surgery by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) scale "physical functioning". The primary efficacy analysis will be conducted for the intention-to-treat population. An analysis of covariance (ANCOVA) model will be applied for the intervention group comparison adjusting for age, centre and EORTC QLQ-C30 scale "physical functioning" before surgery. The level of significance is set at 5% (two-sided) and sample size is determined to assure a power of 1-beta = 90%.

Key secondary outcome(s)
Exploratory analyses

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Patients (no age or gender restrictions) with chronic pancreatitis of the head and pain, eligible for elective surgical resection
2. Ability of subject to understand character and individual consequences of the clinical trial
3. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
Participation in another intervention-trial with interference of intervention and outcome of this study

Date of first enrolment
18/05/2009

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
United Kingdom

Germany

Netherlands

Slovenia

Study participating centre

Im Neuenheimer Feld 110
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Germany
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Sponsor information

Organisation
Study Centre of the German Surgical Society (SDGC) (Germany)

ROR
https://ror.org/00ew91p29

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: ChroPac SE 1682/2-1)

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	09/09/2017		Yes	No
Protocol article	protocol	29/04/2010		Yes	No