

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

Submission date 21/04/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/08/2018	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
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)

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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 $1 - \beta = 90\%$.

Secondary outcome measures

Exploratory analyses

Overall study start date

18/05/2009

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

Age group

Other

Sex

Both

Target number of participants

200

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

Germany

Netherlands

Slovenia

United Kingdom

Study participating centre

Im Neuenheimer Feld 110

Heidelberg

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Sponsor information

Organisation

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

Sponsor details

Klinik für Allgemein-, Viszeral- und Transplantationschirurgie

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Sponsor type

Research organisation

Website

<http://www.klinikum.uni-heidelberg.de/Studienzentrum-der-Deutschen-Gesellschaft-fuer-Chirurgie-SDGC.6107.0.html>

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

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	29/04/2010		Yes	No
Results article	results	09/09/2017		Yes	No