

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

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

**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)

**Study design**

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

**Primary study design**

Interventional

**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  
Heidelberg  
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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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  | results  | 09/09/2017   |            | Yes            | No              |
| <a href="#">Protocol article</a> | protocol | 29/04/2010   |            | Yes            | No              |