

## Summary ChroPac Trial

<b>PRINCIPAL INVESTIGATOR</b>	<b>Markus W. Büchler</b> MD, Professor and Chairman, Dept. of General, Visceral and Trauma Surgery, University of Heidelberg
<b>APPLICANT/COORDINATING INVESTIGATOR</b>	<b>Christoph M. Seiler</b> MD MSc, Consultant Surgeon and Clinical Epidemiologist, Chairman of the Study Centre of the German Surgical Society, Dept. of General, Visceral and Trauma Surgery, University of Heidelberg, Im Neuenheimer Feld 110, D-69120 Heidelberg, Germany, phone: +49-(0)6221-56-6986, fax: +49-(0)6221-56-6988, email: christoph.seiler@med.uni-heidelberg.de
<b>TITLE OF STUDY</b>	Duodenum-preserving head resection versus pancreatico-duodenectomy for chronic pancreatitis of the head – A randomized controlled multicentre trial.
<b>CONDITION</b>	Patients with chronic pancreatitis (CP).
<b>OBJECTIVE(S)</b>	To investigate differences in Quality of Life (QoL) during 24 months after surgery of duodenum-preserving pancreatic head resection (DPPHR) versus pancreatico-duodenectomy (PD).
<b>INTERVENTION (S)</b>	<p><u>Experimental intervention:</u> Any surgical technique that removes inflamed pancreatic tissue of the head without resection of the duodenum (e.g. Begers, Frey or Berne procedure).</p> <p><u>Control intervention:</u> Pylorus preserving Whipple procedure.</p> <p><u>Duration of intervention per patient:</u> Approximately between 2 to 7 hours.</p>
<b>KEY INCLUSION AND EXCLUSION CRITERIA</b>	<p><u>Key inclusion criteria:</u></p> <ul style="list-style-type: none"> <li>• Patients with chronic pancreatitis of the head and pain eligible for elective surgical resection</li> <li>• Ability of subject to understand character and individual consequences of the clinical trial</li> <li>• Written informed consent</li> </ul> <p><u>Key exclusion criteria:</u></p> <ul style="list-style-type: none"> <li>• Participation in another intervention-trial with interference of intervention and outcome of this study</li> </ul>
<b>OUTCOME(S)</b>	<p><u>Primary efficacy endpoint:</u> Average EORTC QLQ-C30 physical status score measured 6, 12, and 24 months after surgery.</p> <p><u>Key secondary endpoint(s):</u></p> <ul style="list-style-type: none"> <li>• Relief of further clinical symptoms of chronic pancreatitis (e.g. indigestion, weight loss, endocrine and exocrine pancreatic insufficiency and diabetes mellitus)</li> <li>• Morbidity</li> <li>• Mortality</li> <li>• Operation time and blood loss</li> <li>• Postoperative hospital stay</li> </ul> <p><u>Assessment of safety:</u> Rates of adverse events and serious adverse events (mortality, re-operation, etc.) will be closely monitored.</p>
<b>DURATION OF TREATMENT AND FOLLOW-UP</b>	<p><u>Duration of treatment per patient:</u> 2 to 7 hours, the surgical procedure will vary according to anatomical situation and randomized technique.</p> <p><u>Follow-up per patient:</u> 24 months</p>
<b>STUDY TYPE</b>	Prospective randomized, controlled, observer and patient blinded multicentre surgical trial with two parallel study groups.

<b>STATISTICAL ANALYSIS</b>	<p><u>Efficacy:</u> The primary efficacy endpoint is the average QoL during 24 months after surgery, measured 6, 12, and 24 months after surgery by the EORTC QLQ-C30 physical status score.</p> <p><u>Description of the primary efficacy analysis and population:</u> The primary efficacy analysis will be conducted in the intention-to-treat population and applies a fixed effects linear model adjusting for gender, age, center and EORTC QLQ-C30 physical status score before surgery. Level of significance is set at 5% (two-sided) and sample size is determined to assure a power of 1-<math>\beta</math>=90%.</p> <p><u>Safety:</u> Exploratory analyses of frequencies of adverse events and serious adverse events.</p> <p><u>Secondary endpoints:</u> Exploratory analyses.</p>
<b>SAMPLE SIZE</b>	<p><u>To be assessed for eligibility (n = 400)</u></p> <p><u>To be allocated to trial (n = 200),</u> inclusive about 15% drop out rate</p> <p><u>To be analysed (n = 172)</u></p>
<b>TRIAL DURATION</b>	<p><u>First patient in to last patient out:</u> April 2009 to April 2013, incl. 2 years recruitment followed by 2 years follow up</p> <p><u>Duration of the entire trial:</u> 5 years, incl. prearrangement and analysis</p>
<b>PARTICIPATING CENTERS</b>	<p>The top recruiting centers of the DISPACT-Trial (ISRCTN: 18452029)</p>
<b>PREVIOUS DFG/BMBF PROJECT NUMBER</b>	<p>BMBF 01GH99033 (SDGC Heidelberg)</p>