Summary ChroPac Trial

PRINCIPAL INVESTIGATOR	**Markus W. Büchler** MD, Professor and Chairman, Dept. of General, Visceral and Transplantation Surgery, University of Heidelberg
APPLICANT/COORDINATING INVESTIGATOR	**Markus Diener** MD, Surgeon, Medical Director of the Study Centre of the German Surgical Society, Dept. of General, Visceral and Transplantation Surgery, University of Heidelberg, Im Neuenheimer Feld 110, 69120 Heidelberg, Germany, phone: +49-(0)6221-56-6986, fax: +49-(0)6221-56-6988, email: markus.diener@med.uni-heidelberg.de
TITLE OF STUDY	Duodenum-preserving head resection versus pancreatico-duodenectomy for chronic pancreatitis of the head – A randomized controlled multicentre trial.
CONDITION	Patients with chronic pancreatitis (CP).
OBJECTIVE(S)	To investigate differences in Quality of Life (QoL) during 24 months after surgery of duodenum-preserving pancreatic head resection (DPPHR) versus pancreatico-duodenectomy (PD).
INTERVENTION (S)	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. Duration of intervention per patient: Approximately between 2 to 7 hours
KEY INCLUSION AND EXCLUSION CRITERIA	Key inclusion criteria: • inflammatory pancreatic head enlargement • local complications (e.g. stenosis of the common bile duct and/or main pancreatic duct, duodenal obstruction, compression of retropancreatic vessels) • pain • written informed consent Key exclusion criteria: • participation in another intervention-trial with interference of intervention and outcome of this study • expected lack of compliance
OUTCOME(S)	Primary efficacy endpoint: Average EORTC QLQ-C30 scale “physical functioning” measured pre-operatively and 6, 12 and 24 months after surgery. Key secondary endpoint(s): • relief of further clinical symptoms of chronic pancreatitis (e.g. indigestion, weight loss, endocrine and exocrine pancreatic insufficiency) • morbidity • mortality • operation time • postoperative hospital stay • EORTC QLQ-C30 and PAN 26 subscores Assessment of safety: Rates of complications and serious adverse events (mortality, re-operation, etc.) will be considered.
DURATION OF TREATMENT AND FOLLOW-UP	Duration of treatment per patient: 2 to 7 hours, the surgical procedure will vary according to anatomical situation and randomized technique. Follow-up per patient: 24 months
STUDY TYPE	Prospective randomized, controlled, observer and patient blinded multicentre surgical trial with two parallel study groups.

STATISTICAL ANALYSIS	Efficacy: 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 scale “physical functioning”. Description of the primary efficacy analysis and population: The primary efficacy analysis will be conducted for the intention-to-treat population. An ANCOVA-model will be applied for the intervention group comparison adjusting for age, center 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-β=90%. Secondary endpoints: Safety and exploratory analyses.
SAMPLE SIZE	To be assessed for eligibility (n = 500) To be allocated to trial (n = 250) To be analysed (n = 172)
TRIAL DURATION	First patient in to last patient out: June 2009 to April 2014, incl. 3 years recruitment, followed by 2 years follow up Duration of the entire trial: 72 months, incl. prearrangement and analysis
PARTICIPATING CENTERS	N=19 sites