TITLE	Distal Pancreatectomy – A randomised controlled trial to compare minimal-invasive distal pancreatectomy to open resection (DISPACT-2 Trial)
ACRONYM	DISPACT-2 Trial
TRIAL REGISTRATION NUMBER	DRKS00014011
INDICATION/CONDITION	Patients with benign and malignant lesions of the pancreatic body and tail requiring elective distal pancreatectomy
OBJECTIVE(S)	To evaluate potential differences in clinical and oncological effectiveness, safety, quality of life and costs between minimal-invasive and open distal pancreatectomy. The primary hypothesis is that minimal-invasive distal pancreatectomy (MIDP) is non-inferior to open distal pancreatectomy (ODP) in terms of postoperative mortality and morbidity measured as the comprehensive complication index (CCI) within 3 months after intervention.
TRIAL DESIGN	Randomised controlled open-label non-inferiority multicentre surgical trial with two parallel study groups.
INTERVENTION(S)	Experimental intervention**:** Minimal-invasive distal pancreatectomy (MIDP) Control intervention: Open distal pancreatectomy (ODP)
ELIGIBILITY CRITERIA	Inclusion criteria: – Planned distal pancreatectomy with or without splenectomy for any indication – Patient suitable for both surgical techniques – Age ≥ 18 years – Ability of subject to understand character and individual consequences of the clinical trial – Written informed consent Exclusion criteria: – Patients scheduled for a pancreatic resection other than distal pancreatectomy – Distant organ metastases – Tumour infiltration of the superior mesenteric vein or superior mesenteric artery or hepatic artery or infiltration of adjacent organs – CA 19-9 >1000 IU/ml – ASA >3 – Prior major open upper abdominal surgery – Left-sided portal hypertension – Participation in another interventional trial with interference of intervention and/or outcome of this study – Expected lack of compliance

PRIMARY ENDPOINT	Postoperative mortality and morbidity assessed as comprehensive complication index (CCI) within 3 months after intervention.
SECONDARY ENDPOINT(S)	Operation time, intraoperative blood loss, conversion rate (minimal-invasive group), days on intensive care unit, pain (NRS), mobility, length of hospital stay, pancreas-surgery associated morbidity (pancreatic fistula, delayed gastric emptying, postoperative hemorrhage, intraabdominal fluid collection), surgical site infection, re-intervention rate, re-operation rate, time to return to work or normal daily activities for retired/ non-working patients, time to functional recovery, Quality of Life (EORTC QLQ-C30 and PAN 28 (CP)), incisional hernia rate and DRG case costs. For oncological patients: Survival, R0/R1 resection rates, lymph node count.
STATISTICAL ANALYSIS	Statistical methods used to compare groups for primary and secondary outcomes: Non-inferiority analysis to compare the CCI between the two groups. The primary efficacy analysis will be based on three different analysis sets (as described in 4.) using a linear mixed regression model including centre as random intercept. Descriptive methods will be used for the analysis of the secondary outcomes. Methods for additional analyses, such as subgroup analyses and adjusted analyses: Serious adverse events and adverse events are collected as minor and major complications throughout the study and will be tabulated and compared between groups. Further exploratory analyses include evaluation of confounding factors and subgroup analyses.
SAMPLE SIZE	To be assessed for eligibility: n = 600 To be allocated to trial: n = 294