DISPACT trial: a randomized controlled trial to compare two different surgical techniques of distal pancreatectomy - study rationale and design.

BACKGROUND: Surgery is of increasing importance in the treatment and outcome of diseases of the pancreas worldwide. The incidence of pancreatic cancer (7-11/100,000 per year) has risen over the last years and surgical resection remains the only option for definite cure. Twenty-five percent of all resections are left of the superior mesenteric vein (distal pancreatectomy) and the appropriate closure technique for the pancreatic remnant remains unclear. Pancreatic fistulas are the most common (0-40%) and relevant postoperative complication. The optimal surgical strategy for pancreatic resection needs to be identified from the large number of surgical procedures available today. PURPOSE: To evaluate the effectiveness of the two most common surgical techniques for distal pancreatectomy: stapler versus hand-sewn closure of the pancreatic remnant. METHODS: In order to account for the uncertainty and clinical heterogeneity in the management of the pancreatic remnant following distal pancreatectomy, a study protocol is developed on the basis of a retrospective survey of patients in a center of excellence for pancreatic surgery and a systematic review with meta-analysis. RESULTS: The DISPACT trial is a multicentered, randomized, controlled and patient-and observer-blinded trial using a two-group parallel
group-sequential superiority design to compare the two techniques mentioned above. It will include approximately 336 randomized patients at up to 20 centers of excellence in pancreatic surgery, who are undergoing elective distal pancreatectomy for resectable benign, malign, and neuroendocrine tumors, chronic pancreatitis and pseudocysts of the pancreatic body and tail. The combination of the rate of postoperative pancreatic fistula and mortality will be evaluated as the primary endpoint. In addition, a set of general and surgical parameters will be analyzed. Pre-specified treatment manuals and continuous intra-operative (photo-documentation of surgical procedures and blinded evaluation thereafter) and on-site monitoring will assure that the treatment of the study patients conforms to protocol and will minimize clinical heterogeneity. Due to uncertainties about the effect sizes of the primary endpoint, an a priori planned interim analysis of the primary endpoint will be conducted after 224 evaluable patients are selected in order to reassess the initially planned sample size.

LIMITATIONS: Since pre-existing evidence was limited our initial sample size calculation is based on uncertain assumptions and may need to be modified in a planned interim analysis. Moreover, since surgical experience remains a potential confounder in surgical trials, learning curve bias has to be taken into account when analyzing the results. Given the participating trial sites, standardization of peri-and postoperative treatment represents a major issue of trial conduct. CONCLUSIONS: A group-sequential study design accounts for the uncertainty of pre-existing evidence. Also, standardization of surgical and postoperative care and blinded outcome assessment as well as adjustment for varying surgical expertise will contribute to a high validity and generalizability of the results.

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