PROTOCOL SUMMARY

Protocol Title (Short Title)	*PATCH - DP*
Protocol Number	346-2017
Phase	II
Study Design	Multicentre, single-arm, phase II clinical trial
Study Duration	1 year
Setting	Multicentre
Sample Size	52 patients
Main Inclusion Criteria	Adults ≥18 years of age undergoing distal pancreatectomy +/- splenectomy for any indication
Primary Outcome:	Post-operative pancreatic fistula (ISGPF Grade B/C)
Secondary Outcomes:	Post-operative pancreatic fistula (all grades), Mortality, Readmissions, Re-interventions, Post-operative complications
Investigational Product and Planned Use	HEMOPATCH flexible hemostat applied intraoperatively to the pancreatic stump following distal pancreatectomy

STATISTICAL CONSIDERATIONS

Study Hypothesis

We hypothesize that application of the HEMOPATCH pad to the pancreatic stump following DP will decrease the incidence of clinically significant (ISGPF Grade B/C) post-operative pancreatic fistulas.

Sample Size Considerations

Operative application of HEMOPATCH will be considered effective at reducing the rate of POPF if there is a 50% relative reduction in the incidence of Grade B/C POPF. Assuming a baseline Grade B/C POPF rate of 20%, in order to detect an absolute reduction of 10% with power of 0.80 and alpha of 0.05, a total sample size of 398 patients would be required for a definitive phase III trial.

For this trial, we used a one-sample test for proportion. The null hypothesis that the true rate of Grade B/C POPF is 20% will be tested against the alternative hypothesis of a 10% rate of POPF in patients undergoing application of HEMOPATCH. A total of 52 patients in the study group is required, assuming a type I error rate of 0.20 and a power of 0.75 (*a priori* thresholds for proceeding to a definitive phase 3 randomized trial) when the true rate of Grade B/C POPF is 10% in the study group.

Stopping Rules

This study will be stopped prior to its completion if: (1) the intervention is associated with adverse events that call into question the safety of the intervention; (2) difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints; (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping the trial.

Analysis Plan

Descriptive statistics will be used to examine the baseline characteristics of included and excluded participants. Mean and standard deviations will be reported for all characteristics expressed as continuous variables. Medians and ranges will be presented for discrete data.

The primary outcome is incidence of Grade B/C POPF. Comparison of incidence of Grade B/C POPF in the study population will be made to the baseline rate of 20% by unadjusted one-sample test for proportion. Rates of all secondary outcomes will be calculated along with 95% confidence intervals.