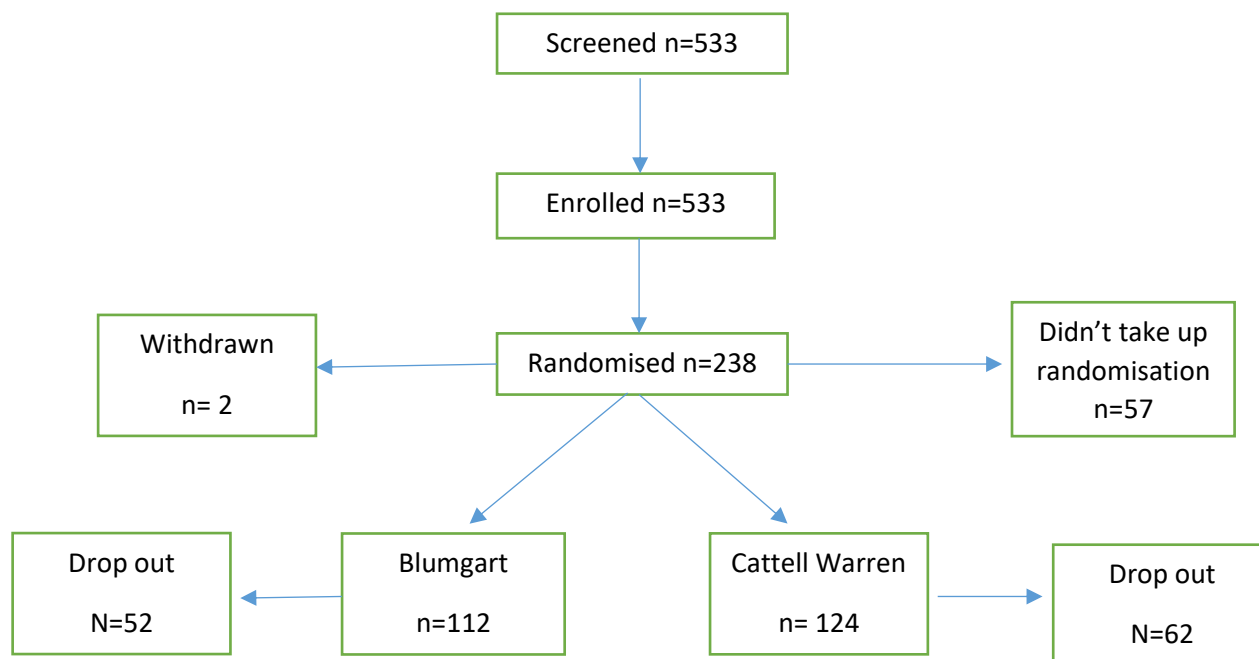


Participant Flow



Baseline Characteristics

Factor	Level	Blumgart (n=112)	Cattell Warren (n=124)
Age	Median (IQR)	70 (61.5 to 74)	70 (62.5 to 76)
Gender [n,(%)]	Female	42 (38%)	45 (36%)
	Male	70 (63%)	79 (64%)
Days to surgery since enrolment	Median (IQR)	1 (0 to 2)	1 (0 to 1.5)
Days to surgery since date of suspected diagnosis	Median (IQR)	33 (20 to 49)	33 (21 to 48.5)
Smoking status [n,(%)]	Ever	73 (65%)	74 (60%)
	Never	39 (35%)	50 (40%)
	Missing	0 (0%)	0 (0%)
Alcohol status [n,(%)]	None	40 (36%)	34 (27%)
	Sporadic	43 (38%)	51 (41%)
	Regular	20 (18%)	31 (25%)
	Excessive	9 (8%)	6 (5%)
	Missing	0 (0%)	2 (1%)
Physical Findings			
Pancreatic texture* [n,(%)]	Normal/Hard	67 (59%)	67 (54%)
	Soft	46 (41%)	58 (46%)
Pancreatic duct diameter [n,(%)]	Non Dilated (<=3mm)	73 (65%)	76 (61%)
	Dilated	40 (35%)	49 (39%)
Diabetic Status [n,(%)]	None	93 (83%)	98 (79%)
	Type 1	0 (0%)	5 (4%)

Factor	Level	Blumgart (n=112)	Cattell Warren (n=124)
	Type 2	14 (13%)	14 (11%)
	Type 2 (on insulin)	4 (4%)	7 (6%)
	missing	1 (0%)	0 (0%)
Pancreatic Endocrine Insufficiency [n,(%)]	No	2 (2%)	1 (1%)
	Yes (requiring treatment)	63 (56%)	46 (37%)
	Missing	47 (20%)	77 (33%)

Outcome Measures

Primary Outcome: Post-operative pancreatic fistula.

Arm	Total Randomised	Total number of events	Rate of POPF	Odds Ratio (95% CI) ²	p-value
Blumgart	112	28	0.25 (0.17, 0.33)	1.04 (0.58 – 1.88)	0.887
Cattell-Warren	124	32	0.26 (0.18, 0.34)		

Secondary Outcome: Time to entry into adjuvant therapy programs

Arm	Total Analysed	3 months	6 months	9 months	12 months	Total started adjuvant therapy	%
Blumgart	66	27	14	12	5	59	77%
Cattell-Warren	71	33	19	18	8	53	75%

Secondary outcome: Mortality rate

Arm	Total Randomised	Total number of deaths
Blumgart	112	24
Cattell - Warren	124	20

Secondary outcome: Rate of Delayed Gastric Emptying

Treatment	Total	Events	Prop.	Prop. CI	OR	OR CI	P-value
Blumgart	111	34	0.31	(0.22 - 0.39)			
Cattell-Warren	123	40	0.33	(0.24 - 0.41)	1.09	(0.63 - 1.9)	0.756

Secondary outcome: Rate of Wound Infection

Treatment	Total	Events	Prop.	Prop. CI	OR	OR CI	P-value
Blumgart	111	24	0.22	(0.14 - 0.29)			
Cattell-Warren	123	19	0.15	(0.09 - 0.22)	0.66	(0.34 - 1.29)	0.225

Secondary outcome: Rate of Pulmonary Infection

Treatment	Total	Events	Prop.	Prop. CI	OR	OR CI	P-value
Blumgart	111	14	0.13	(0.06 - 0.19)			
Cattell-Warren	123	8	0.07	(0.02 - 0.11)	0.48	(0.19 - 1.2)	0.116

Secondary outcome: Post-Operative Fluid Collection

Treatment	Natural Scale	Log(x+1) scale
Blumgart Anastomosis	238 (52.5, 774.5)	5.472 (3.96, 6.652)
Cattell-Warren Anastomosis	237 (45, 1129.5)	5.468 (3.806, 7.025)
Total	237.5 (48.5, 1006.5)	5.47 (3.881, 6.914)

Secondary outcome: Re-Operation Rate

Treatment	Total	Events	Prop.	Prop. CI	OR	OR CI	P-value
Blumgart	102	9	0.09	(0.03 - 0.14)			
Cattell-Warren	115	5	0.04	(0.01 - 0.08)	0.47	(0.15 - 1.45)	0.189

Secondary outcome: Rate of Venous Thrombo-embolism

Treatment	Total	Events	Prop.	Prop. CI	OR	OR CI	P-value
Blumgart	111	7	0.06	(0.02 - 0.11)			
Cattell-Warren	123	3	0.02	(0 - 0.05)	0.37	(0.09 - 1.47)	0.159

Secondary outcome: Rate of Post-Operative Bleed

Treatment	Total	Events	Prop.	Prop. CI	OR	OR CI	P-value
Blumgart	111	24	0.22	(0.14 - 0.29)			
Cattell-Warren	123	19	0.15	(0.09 - 0.22)	0.66	(0.34 - 1.29)	0.225

Secondary outcome: Intra-Operative Bleed

Treatment	Blood Loss
Blumgart	560 (400, 900)
Cattell-Warren	600 (453.75, 903.75)
Total	600 (400, 900)

Secondary Outcome: Length of Hospital Stay

Arm	Total Randomised	Mean (SD)	Median(IQR)	Mean difference (95% CI)	p-value
Blumgart	112	18.49 (12.70)	13.0 (10 - 24)		
Cattell Warren	124	21.11 (19.36)	14.5 (10 - 22)	2.62(-1.69, 6.94)	0.232

Secondary Outcome: Quality of Life

EORTC - QCG30

Time Point	Blumgart Anastomosis	Cattell-Warren Anastomosis	Total
Registration	66.67 (41.67, 83.33)	66.67 (50, 83.33)	66.67 (50, 83.33)
Post-Op Review Discharge	50 (33.33, 66.67)	50 (33.33, 66.67)	50 (33.33, 66.67)
3 Month Follow Up	66.67 (50, 83.33)	66.67 (50, 83.33)	66.67 (50, 83.33)
6 Month Follow Up	75 (50, 83.33)	66.67 (50, 83.33)	66.67 (50, 83.33)
12 Month Follow Up	83.33 (66.67, 83.33)	75 (58.33, 83.33)	75 (58.33, 83.33)

EQ5D

Time Point	Blumgart Anastomosis	Cattell-Warren Anastomosis	Total
Registration	71 (60, 90)	77 (60, 90)	75 (60, 90)
Post-Op Review Discharge	60 (50, 75)	62.5 (50, 80)	60 (50, 80)
3 Month Follow Up	70 (60, 85)	75 (60, 86)	75 (60, 85)
6 Month Follow Up	76 (70, 85.25)	71.5 (60, 81.25)	75 (63.25, 85)
12 Month Follow Up	80 (70, 90)	80 (60.75, 90)	80 (70, 90)

Adverse Events

Summary of Serious Adverse Events

	Number of Events	Number of Patients	Grade				
			1	2	3	4	5
Blumgart Anastomosis	18	15	11	2	0	0	5
Cattell-Warren Anastomosis	21	16	13	1	2	2	3

Line Listing of Serious Adverse Events Observed

Outcome	Overall Diagnosis	Grade	Arm
Resolved	Post-operative bleeding from drains - reoperated	IV	Blumgart Anastomosis
Resolved	Head Injury	II	Blumgart Anastomosis
Resolved	Splenic Injury	IVad	Blumgart Anastomosis
Resolved	Hospital Acquired Pneumonia	IVa	Blumgart Anastomosis
Fatal	Hospital Acquired Pneumonia	Vd	Blumgart Anastomosis
Resolved	Bleeding vessel in Right colonic mesentary	IVad	Blumgart Anastomosis
Fatal	Upper GI Bleed	IV	Blumgart Anastomosis
Fatal	DEATH FROM ISHCAEMIC SMALL BOWEL GRADE 5	V	Blumgart Anastomosis
Fatal	Respiratory Failure Grade V	V	Blumgart Anastomosis
Resolved	Post procedure pancreatitis	IIIb	Blumgart Anastomosis
Resolved with Sequelea	Massive Myocardial Infarct	IVa	Blumgart Anastomosis
Fatal	Post Op Bleeding	Vd	Blumgart Anastomosis
Resolved	Haematoma (Wound)	II	Blumgart Anastomosis
Resolved	Ventricular Fibrillation Arrest	IVb	Blumgart Anastomosis

Outcome	Overall Diagnosis	Grade	Arm
Resolved	Left Pneumothorax	IIIa	Blumgart Anastomosis
Resolved with Sequelea	Intra-abdominal sepsis IVb	IVb	Blumgart Anastomosis
Resolved	Aspiration Pneumonia Grade III	IVb	Blumgart Anastomosis
Resolved	RIGHT LOWER ZONE HOSPITAL ACQUIRED PNEUMONIA. RIGHT UPPER ZONE PNEUMOTHORAX (RESOLVED SPONTANEOUSLY)	IIIa	Blumgart Anastomosis
Resolved with Sequelea	Respiratory Failure	IVa	Cattell-Warren Anastomosis
Resolved	Intra Abdominal Abscess	IIIa	Cattell-Warren Anastomosis
Fatal	Liver Metastases (grade 4)	Vd	Cattell-Warren Anastomosis
Resolved	Foot Drop left	IIIa	Cattell-Warren Anastomosis
Resolved	Acute Kidney Injury (Grade 2)		Cattell-Warren Anastomosis
Resolved	Post-operative Bleeding	IVbd	Cattell-Warren Anastomosis
Resolved	Pulmonary Embolism	IVb	Cattell-Warren Anastomosis
Resolved	Bile Leak	IIIa	Cattell-Warren Anastomosis
Resolved	Post Operative Bleed	IV	Cattell-Warren Anastomosis
Ongoing	GDA bleed Pancreatic Ischemia Grade 4	IV	Cattell-Warren Anastomosis
Ongoing at Death	Abdo Wall Dehiscence// GI breakdown	IV	Cattell-Warren Anastomosis
Ongoing at Death	Recurring Liver Abscess - ongoing sepsis - death	Vd	Cattell-Warren Anastomosis
Resolved	Respiratory Failure	IV	Cattell-Warren Anastomosis
Fatal	Death.	Vd	Cattell-Warren Anastomosis
Fatal	POST OPERATIVE PANCREATIC FISTULA GRADE C	Vd	Cattell-Warren Anastomosis

Outcome	Overall Diagnosis	Grade	Arm
Resolved	BLEEDING / RETURN TO THEATRE	IVbd	Cattell-Warren Anastomosis
Resolved	Colonic Fistula Grade 4	IVd	Cattell-Warren Anastomosis
Resolved	Type 1 respiratory failure Grade IVa	IVd	Cattell-Warren Anastomosis
Resolved	Respiratory failure. AKI STAGE 3	IVbd	Cattell-Warren Anastomosis
Resolved	Retained Foreign Body Grade 3b	IIIb	Cattell-Warren Anastomosis
Ongoing	Unspecified encephalopathy	IVad	Cattell-Warren Anastomosis

