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Cattell-
Warren versus Blumgart techniques of pancreatic

Submission date 14/01/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/01/2015	**Overall study status** Completed	
Last Edited 17/02/2023	**Condition category** Digestive System	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-two-different-ways-of-joining-the-pancreas-to-the-bowel-during-surgery-for-pancreatic-cancer-panasta

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

17639

Study information

Scientific Title
Cattell-Warren versus Blumgart techniques of pancreatico-jejunostomy following pancreato--duodenectomy: -a double blinded multicentred trial

Acronym
PANasta

Study objectives
This study will aim to compare the effectiveness of two techniques of pancreaticojejunostomy; Cattell-Warren versus Blumgart follwing pancreatoduodenectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester South, 22/12/2014, ref: 14/NW/1393

Study design
Randomised; Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cancer, Surgery, Gastroenterology; Subtopic: Upper Gastro-Intestinal Cancer, Surgery, Gastroenterology; Disease: Pancreas

Interventions
1. Blumgart anastomosis, Re-construction of the pancreatic remnant following pancreato-duodenectomy using a Blumgart method
2. Cattell-Warren anastomosis, Re-construction of the pancreatic remnant following pancreato-duodenectomy using a Cattell-Warren method of pancreatico-jejunostomy

Intervention Type

Procedure/Surgery

Primary outcome measure
Post-operative pancreatic fistula (POPF); Timepoint(s): Post-operative day 3, 5, 7, discharge and 3 month follow up

Secondary outcome measures
1. Entry into programs of adjuvant therapy / clinical trials of adjuvant therapy; Timepoint(s): 3, 6 and 12 month follow up;
2. Health economic evaluation; Timepoint(s): Enrolment, discharge ad 3, 6 and 12 month follow up
3. Length of hospital stay; Timepoint(s): Discharge, 3, 6 and 12 month follow up
4. Mortality Rate; Timepoint(s): Death due to any cause during the study period will be recorded
5. Operation time; Timepoint(s): Day of surgery
6. Quality of Life; Timepoint(s): Enrolment, discharge and 3, 6 and 12 month follow up
7. Rate of delayed gastric emptying; Timepoint(s): Post-operative day 3, 5, 7 and discharge
8. Rate of intra and post-operative bleeding; Timepoint(s): day of surgery, post-operative day 3, 5, 7 and discharge
9. Rate of post-operative fluid collections; Timepoint(s): Post-operative day 3, 5, 7, discharge and 3 month follow up
10. Rate of pulmonary infection; Timepoint(s): Discharge and 3 month follow up
11. Rate of re-operation; Timepoint(s): Post-operative day 3, 5, 7, discharge and 3, 6 and 12 month follow up
12. Rate of venous thrombo-embolism; Timepoint(s): Post-operative day 3, 5, 7 and discharge and 3, 6 and 12 month follow up
13. Rate of wound infections; Timepoint(s): Post-operative days 3, 5, 7, discharge and 3, 6 and 12 month follow up

Overall study start date
01/07/2014

Completion date
01/02/2019

Eligibility

Key inclusion criteria
Subjects meeting all of the following criteria will be considered for this trial:
1. Patients undergoing an elective pancreato
duodenectomy for presumed malignancy of the head of the pancreas
2. Ability of the subject to understand the nature and consequences of the trial
3. Ability to provide written informed consent.; Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Planned Sample Size: 506; UK Sample Size: 506; Description: The total sample of 506 patients (253 in each arm) has been calculated to detect a 10% attrition rate of 5%. Non-compliance would occur in the event of unresectable disease, assumed at 10%.

Key exclusion criteria
Subjects with the following criteria will not be entered into this trial:
1. Patients undergoing extended pancreato-duodenectomy
2. Left, central or total pancreatectomy
3. Arterial resection or multi-visceral resection
4. Previous pancreatic resection
5. Surgery for known chronic pancreatitis
6. Recruited to any other pancreatic resection trial.
7. Pregnant women

Date of first enrolment
24/04/2015

Date of final enrolment
02/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool
Cancer Research UK Liverpool Cancer Trials Unit
1st floor Block C
Waterhouse Building
3 Brownlow Street
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L69 3GL

Sponsor information

Organisation
University of Liverpool

Sponsor details
Foresight Centre
1-3 Brownlow Street
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England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 10/02/2020:
Planned clinical case study report, publication in peer-reviewed scientific journals, and conference presentations in May/June 2020.

Previous publication and dissemination plan:
To be confirmed at a later date

Intention to publish date
01/04/2020

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/01/2016		Yes	No
Basic results		14/01/2021	15/01/2021	No	No
Plain English results			17/02/2023	No	Yes
HRA research summary			28/06/2023	No	No