

Cattell-Warren versus Blumgart techniques of pancreatic

Submission date 14/01/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/02/2023	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 following 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 and 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 pancreateo-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
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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