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PRIMUS001: A study looking at two different treatments for pancreatic cancer that has spread to other parts of the body

Submission date 30/05/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 31/05/2017	**Overall study status** Completed	
Last Edited 08/04/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-folfox-a-chemotherapy-for-cancer-of-the-pancreas-that-has-spread-primus-001

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Additional identifiers

Clinical Trials Information System (CTIS)
2016-004155-67

Integrated Research Application System (IRAS)
221370

ClinicalTrials.gov (NCT)
NCT04151277

Protocol serial number
PRIMUS0012016, IRAS 221370

Study information

Scientific Title
PRIMUS 001: An adaptive phase II study of FOLFOX-A (FOLFOX and nab-paclitaxel) versus AG (nab-paclitaxel and gemcitabine) in patients with metastatic pancreatic cancer, with integrated biomarker evaluation

Acronym
PRIMUS 001

Study objectives
That FOLFOX-A will increase progression free survival in metastatic pancreatic cancer patients over AG

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/08/2017, West of Scotland REC (Dykebar Hospital, Glasgow, PA2 7DE, United Kingdom; +44 141 314 0211; Ruth.Hood2@ggc.scot.nhs.uk), ref: 17/WS/0142

Study design
Multi-centre randomised open label two arm phase II trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metastatic pancreatic cancer

Interventions
Patients will call the CTU to randomise the patients and they will be randomised on a 1:1 basis with 50% receiving AG and 50% FOLFOX-A. Minimisation will be used to allocate patients between the treatment arms, the following factors will be used: treatment centre, whether or not the patient has liver metastasis, whether the primary tumour is in the head or the tail of the pancreas and the patients baseline CA19.9.

FOLFOX-A (nab-paclitaxel 150mg/m2 IV over 30 minutes, day 1 (administered first), Oxaliplatin: 85mg/m2, IV over 2 hours, day 1, Folinic acid: 350 mg flat dose or 400mg/m2, IV over 2 hours, day 1 (as per standard of care for folinic acid dosing), 5-FU infusion:1200mg/m2/day, as a continuous IV infusion over 2 days, day 1 and day 2 (for a total dose of 2400mg/m2 over 46 hours.)

OR

AG (nab-paclitaxel: 125 mg/m2 IV over 30 minutes, day 1,8, and 15 (administered first and Gemcitabine 1000 mg/m2 IV over 30 mins on days 1, 8, and 15 (immediately following nab-paclitaxel).

When the patient progressed on CT scan treatment will stop and the end of treatment visit will take place with 28 days of the last treatment. At this visit any con meds will be reviewed, physical exam (weight, BP, pulse), ECOG, blood count and biochemistry, assessment of adverse events, CA19.9 and quality of life.

After that patients will be followed up every 3 months for the first year post randomisation, 18 months after randomisation, 24 months and then annually for up to 5 years. At these visits con meds, including any new cancer treatments will be recorded, ECOG, CA19.9, quality of life assessments and survival status will be recorded.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Nab-paclitaxel, gemcitabine, oxaliplatin, folinic acid, 5-fluorouracil

Primary outcome(s)
Progression free survival as measured by IV contrast enhanced CT scan every 8 weeks from the date of randomisation to progression or death (from any cause), whichever occurs first.

Key secondary outcome(s))

1. Objective response rate based on RECIST v1.1 will be measured by contrast enchanged CT scan every 8 weeks until disease progression
2. Overall survival will be recorded at each study visit up to 60 months post randomisation
3. Safety and tolerability will be assessed using NCI-CTCAE v4. Adverse events will be collected at each treatment visit and the end of treatment visit.
4. Quality of life will be assessed using EORTC QLQ-C30, QLQ PAN26, ED-5D-5L monthly while on treatment and then at each follow up visit
5. Peripheral neuropathy will be assessed by the GOG-NTX4 questionnaire monthly while on treatment and then at each follow up visit
6. Health Economics: Resource use will be assessed by the EQ-5d-5L monthly while on treatment and then at each follow up visit. Information will also be collected regarding any inpatients stays in hospital during the course of the study

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. Patient has been enrolled in the Precision Panc Master Protocol and their tissue has been deemed suitable for NGS analysis
2. Patient has provided signed information consent for the PRIMUS 001 study
3. Age 16 years and over
4. Histologically-confirmed metastatic pancreatic ductal adenocarcinoma and its varients, with measurable metastatic lesion(s) according to RECIST 1.1.
5. Eastern Cooperative Oncology Group (ECOG) 0-1 with life expectation of no less than 12 weeks.
6. Patients must have received no previous chemotherapy or investigational therapy for the treatment of metastatic disease. Prior treatment with a fluoropyrimidine and/or gemcitabine administered in the adjuvant setting is allowed, provided at least 6 months have elapsed since completion of the last dose and no ongoing toxicities are present.
7. Adequate liver/bone marrow function as defined by:
7.1. Neutrophils (ANC) ≥ 1.5 x 109/l
7.2. Platelets ≥ 100 x 109/l
7.3. Haemoglobin ≥ 9.0 g/dL
7.4. WBC ≥ 3 x 109/l
7.5. Total bilirubin ≤ 1.5 x institutional ULN unless bilirubin rise is due to Gilbert’s syndrome
7.6. Aspartate transaminase (AST) and alanine aminotransferase (ALT) ≤ 2.5 x ULN (and <5 ULN in the presence of liver metastases)
7.7. Estimated creatinine clearance ≥ 60 mL/min (as calculated by Cockcroft and Gault or Wright formula or measured by EDTA clearance)
8. Negative serum Human Chorionic Gonadotropin (HCG) test for females with child bearing potential. Postmenopausal women must have been amenorrhoeic for at least 12 months to be considered of non-childbearing potential
9. Woman of child bearing potential, and men with female partners of child bearing potential, must agree to use adequate contraceptive measures (see section 8.1.8.1) for the duration of the study and for up to 6 months after the completion of study treatment.
10. Compliant, and can be followed up regularly

The following additional inclusion criteria is ONLY required if recommended by the independent Data Monitoring Committee after interim review of study data (sites will have been informed by the CRUK CTU if this is the case):
11. Patient must be biomarker positive as fed back after central Precision-PANC diagnostic testing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 12/03/2024:

1. Prior treatment with nab-paclitaxel or oxaliplatin
2. Prior chemotherapy for metastatic pancreatic cancer
3. Known hypersensitivity for any component of any study drug
4. Active infection including Herpes Zoster and chickenpox
5. Current neuropathy ≥ grade 2
6. Uncontrolled brain metastatsis or mental illness
7. Uncontrolled congestive heart failure (CHF), or history of myocardial ischemia (MI), unstable angina, stroke, or transient ischemia within previous 6 months.
8. Uncontrolled serious contraindicated medical condition or illness
9. Known or suspected dihydropyrimidine (DPD) deficiency
10. Pregnant of breastfeeding
11. History of physical or psychiatric disorder that would prevent informed consent and compliance with protocol
12. Administration of any investigational drug within 28 days or 5 half-lives, whichever is longer, of receiving the first dose of trial treatment
13. Any systemic anti-cancer therapy, or major surgery within 28 days of randomisation
14. Any minor surgery or radiotherapy within 7 days of randomisation
15. Any psychological, familial, sociological or geographical consideration potentially hampering compliance with the trial protocol and follow up schedule.
16. Any patients receiving treatment with brivudin, sorivudin and analogues
17. History of another malignancy in the last 3 years (other than treated squamous/basal cell skin cancer, treated early-stage cervical cancer or treated/biochemically-stable, organ-confined prostate cancer)
19. Any patient with severe diarrhoea (defined as ≥grade 3 diarrhoea despite maximum supportive measures and exclusion of underlying infection

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Previous exclusion criteria:

1. Prior treatment with nab-paclitaxel or oxaliplatin
2. Prior chemotherapy for metastatic pancreatic cancer
3. Known hypersensitivity for any component of any study drug
4. Active infection including Herpes Zoster and chickenpox
5. Current neuropathy ≥ grade 2
6. Uncontrolled brain metastatsis or mental illness
7. Uncontrolled congestive heart failure (CHF), or history of myocardial ischemia (MI), unstable angina, stroke, or transient ischemia within previous 6 months.
8. Uncontrolled serious contraindicated medical condition or illness
9. Known or suspected dihydropyrimidine (DPD) deficiency
10. Pregnant of breastfeeding
11. History of physical or psychiatric disorder that would prevent informed consent and compliance with protocol
12. Administration of any investigational drug within 28 days or 5 half-lives, whichever is longer, of receiving the first dose of trial treatment
13. Any systemic anti-cancer therapy, or major surgery within 28 days of randomisation
14. Any minor surgery or radiotherapy within 7 days of randomisation
15. Any psychological, familial, sociological or geographical consideration potentially hampering compliance with the trial protocol and follow up schedule.
16. Any patients receiving treatment with brivudin, sorivudin and analogues
17. History of another malignancy in the last 5 years (other than treated squamous/basal cell skin cancer, treated early-stage cervical cancer or treated/bio
18. Chemically-stable, organ-confined prostate cancer)
19. Any patient with severe diarrhoea (defined as ≥grade 3 diarrhoea despite maximum supportive measures and exclusion of underlying infection

Date of first enrolment
01/09/2017

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre

Beatson West of Scotland Cancer Centre
1053 Great Western Road
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Study participating centre
Addenbrooke's Hospital
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CB2 0QQ

Study participating centre
Bristol Haematology and Oncology Centre
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Study participating centre
The Christie NHS Foundation Trust
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Study participating centre
Guy's Hospital
Great Maze Pond
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SE1 9RT

Study participating centre
Ninewells Hospital and Medical School
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DD1 9SY

Study participating centre
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Study participating centre
Royal Marsden Hospital
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Study participating centre
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Study participating centre
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Study participating centre
Clatterbridge Cancer Centre - Aintree
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Celgene

Alternative Name(s)
Celgene Corporation

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.
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IPD sharing plan summary
Available on request