

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/05/2017	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/04/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English Summary

<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>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number
2016-004155-67

IRAS number
221370

ClinicalTrials.gov number
NCT04151277

Secondary identifying numbers
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 hypothesis
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Condition

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 measure

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.

Secondary outcome measures

1. Objective response rate based on RECIST v1.1 will be measured by contrast enhanced 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

Overall study start date

01/04/2017

Overall study end date

31/07/2025

Eligibility

Participant 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 variants, 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) $\geq 1.5 \times 10^9/\text{l}$
 - 7.2. Platelets $\geq 100 \times 10^9/\text{l}$
 - 7.3. Haemoglobin $\geq 9.0 \text{ g/dL}$
 - 7.4. WBC $\geq 3 \times 10^9/\text{l}$
 - 7.5. Total bilirubin $\leq 1.5 \times$ institutional ULN unless bilirubin rise is due to Gilbert's syndrome
 - 7.6. Aspartate transaminase (AST) and alanine aminotransferase (ALT) $\leq 2.5 \times$ 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

Age group

Mixed

Lower age limit

16 Years

Sex

Both

Target number of participants

460

Participant 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 \geq grade 2
6. Uncontrolled brain metastasis 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 or 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 \geq grade 3 diarrhoea despite maximum supportive measures and exclusion of underlying infection)

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 \geq grade 2
6. Uncontrolled brain metastasis 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 or 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 \geq grade 3 diarrhoea despite maximum supportive measures and exclusion of underlying infection)

Recruitment start date

01/09/2017

Recruitment end date

31/12/2024

Locations

Countries of recruitment

England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre

Beatson West of Scotland Cancer Centre

1053 Great Western Road

Glasgow

United Kingdom

G20 9JG

Study participating centre

Addenbrooke's Hospital

Hills Road

Cambridge

United Kingdom

CB2 0QQ

Study participating centre

Bristol Haematology and Oncology Centre

Horfield Road

Bristol

United Kingdom

BS2 8ED

Study participating centre

The Christie NHS Foundation Trust

550 Wilmslow Road

Manchester

United Kingdom

M20 4BX

Study participating centre

Guy's Hospital

Great Maze Pond

London

United Kingdom

SE1 9RT

Study participating centre
Ninewells Hospital and Medical School
Dundee
United Kingdom
DD1 9SY

Study participating centre
Northern Ireland Cancer Centre
Belfast City Hospital
10 Jubilee Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Royal Marsden Hospital
Downs Road
Sutton
United Kingdom
SM2 5PT

Study participating centre
St George's Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
University College Hospital
235 Euston Road
Bloomsbury
London
United Kingdom
NW1 2PG

Study participating centre
University Hospital Southampton
Tremona Road

Southampton
United Kingdom
So16 6YD

Study participating centre

Castle Hill Hospital

Castle Road
Cottingham
United Kingdom
HU16 5JQ

Study participating centre

Churchill Hospital

Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre

Clatterbridge Cancer Centre - Aintree

Aintree Clatterbridge Cancer Centre
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7AL

Study participating centre

Huddersfield Royal Infirmary

25 Acre Street
Lindley
Huddersfield
United Kingdom
HD3 3EA

Study participating centre

Milton Keynes General Hospital

Milton Keynes Hospital
Standing Way
Eaglestone

Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Norfolk and Norwich Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Raigmore Hospital
Old Perth Rd
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Royal Cornwall Hospitals & West Cornwall Hospital
Royal Cornwall Hospitals NHS Trust
Treliske Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
The Royal Marsden Hospital
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
Singleton Hospital
Sketty Lane
Sketty
Swansea
United Kingdom
SA2 8QA

Study participating centre
St Bartholomews Hospital
New Road
Rochester
United Kingdom
ME1 1DS

Study participating centre**St James's University Hospital NHS Trust**

St James's University Hospital
Gledow Wing
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre**Velindre Cancer Centre**

Velindre Road
Cardiff
United Kingdom
CF14 2TL

Study participating centre**Western General Hospital**

Crewe Road South
Edinburgh
Lothian
United Kingdom
EH4 2XU

Study participating centre**Weston Park Hospital Cancer Centre**

Whitham Road
Broomhall
Sheffield
United Kingdom
S10 2SJ

Study participating centre**University Hospitals Coventry and Warwickshire NHS Trust**

Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation

NHS Greater Glasgow and Clyde

Sponsor details

West Glasgow Ambulatory Care Hospital

Dalnair Street

Glasgow

Scotland

United Kingdom

G3 8SJ

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05kdz4d87>

Funder(s)**Funder type**

Charity

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

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

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

31/01/2026

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