

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

<b>Submission date</b> 30/05/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/05/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/04/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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>

## Contact information

### Type(s)

Scientific

### Contact name

Ms Sarah Bradley

### Contact details

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### Type(s)

Public

### Contact name

Ms Sarah Bradley

### Contact details

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

OR

AG (nab-paclitaxel: 125 mg/m<sup>2</sup> IV over 30 minutes, day 1,8, and 15 (administered first and Gemcitabine 1000 mg/m<sup>2</sup> 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 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

## **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 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  $\geq 60 \text{ mL/min}$  (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  $\geq$  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)

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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  $\geq$  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

## 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  
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

**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.

Caroline.Kelly@glasgow.ac.uk

## IPD sharing plan summary

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes