ISRCTN75002153 https://doi.org/10.1186/ISRCTN75002153

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

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

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Scientific

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Public

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# Additional identifiers

### ClinicalTrials.gov (NCT)
NCT04151277

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

### Integrated Research Application System (IRAS)
221370

### Protocol serial number
PRIMUS0012016

# 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
Glasgow
United Kingdom
G20 9JG

**Study participating centre**
**Addenbrooke's Hospital**
Hills Road
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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
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United Kingdom
SM2 5PT

**Study participating centre**
**St George's Hospital**
Blackshaw Road
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SW17 0QT

**Study participating centre**
**University College Hospital**
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**Study participating centre**
**University Hospital Southampton**
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United Kingdom
So16 6YD

**Study participating centre**
**Castle Hill Hospital**
Castle Road

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United Kingdom
HU16 5JQ

**Study participating centre**
**Churchill Hospital**
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

**Study participating centre**
**Clatterbridge Cancer Centre - Aintree**
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Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7AL

**Study participating centre**
**Huddersfield Royal Infirmary**
25 Acre Street
Lindley
Huddersfield
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HD3 3EA

**Study participating centre**
**Milton Keynes General Hospital**
Milton Keynes Hospital
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Eaglestone
Milton Keynes
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MK6 5LD

**Study participating centre**
**Norfolk and Norwich Hospital**
Colney Lane

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NR4 7UY

**Study participating centre**
**Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus**
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**Study participating centre**
**University Hospitals Dorset NHS Foundation Trust**
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**Study participating centre**
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**Study participating centre**
**Raigmore Hospital**
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**Study participating centre**
**Royal Cornwall Hospitals & West Cornwall Hospital**
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**Study participating centre**
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**The Royal Marsden Hospital**
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**Study participating centre**
**St Bartholomews Hospital**
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**Study participating centre**
**St James's University Hospital NHS Trust**
St James's University Hospital
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**Study participating centre**
**Velindre Cancer Centre**
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CF14 2TL

**Study participating centre**
**Western General Hospital**
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Lothian
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EH4 2XU

**Study participating centre**
**Weston Park Hospital Cancer Centre**
Whitham Road
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United Kingdom
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**Study participating centre**
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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.
Caroline.Kelly@glasgow.ac.uk

**IPD sharing plan summary**
Available on request