

# Adults with Acute Myeloid Leukaemia or High-Risk Myelodysplastic Syndrome (AML19)

<b>Submission date</b> 30/09/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/12/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/10/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-different-treatments-for-acute-myeloid-leukaemia-and-high-risk-myelodysplastic>

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-treatment-for-acute-promyelocytic-leukaemia-aml-19>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Nigel Russell

### Contact details

Nottingham University  
Haematology Department  
Hucknall Road  
Nottingham  
United Kingdom  
NG5 1PB

-  
nigel.russell@nottingham.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

2014-002195-90

### Protocol serial number

SPON1334-04

# Study information

## Scientific Title

Adults with Acute Myeloid Leukaemia or High-Risk Myelodysplastic Syndrome (AML19): a randomised, controlled, open label Phase III trial

## Acronym

AML19

## Study objectives

Current study hypothesis as of 25/02/2021:

Primary Objective:

To compare overall survival in patient groups of differing risk status by assessing time from randomisation into particular arms of the study until death from any cause

Secondary Objectives:

1. To assess achievement of complete remission (CR) after treatment in all patient groups by calculating time of randomisation until time of first CR
2. To assess duration of CR by reviewing time from first CR to first relapse, and see if rate of relapse varies by treatment group
3. To assess the toxicities experienced in each course of treatment in all patient groups
4. To evaluate the safety and efficacy of Midostaurin in patients with a FLT3 mutation who have received DA chemotherapy combined with Gemtuzumab Ozogamicin (Mylotarg)
5. To assess quality of life in all patient groups

Exploratory Objectives:

To evaluate the therapeutic relevance of morphological, cytogenetic, molecular-genetic (genomic) and immunophenotypic assessments, in particular:

1. The relevance of the molecular and immunophenotypic detection of minimal residual disease
2. To associate molecular genotype (genomics) with clinical outcome
3. To store excess diagnostic material for future research

Previous study hypothesis:

For patients with acute myeloid leukaemia (AML) the aims of the AML19 trial are:

1. To compare four induction chemotherapy schedules (namely DA + Mylotarg (3mg/m<sup>2</sup>) or DA + Mylotarg (3mg/m<sup>2</sup> x2, maximum 5mg per day) versus FLAG-Ida + Mylotarg (3mg/m<sup>2</sup>) or FLAG-Ida + Mylotarg (3mg/m<sup>2</sup> x2, maximum 5mg per day)) in patients who are not known at entry to have adverse cytogenetics
  2. For patients receiving FLAG-Ida to compare one or two courses of HDAC consolidation versus no further treatment
  3. Patients with FLT3 mutations may enter the AML19 pilot trial
  4. To assess the value of Ganetespib in patients who lack a FLT3 mutation and are not high risk
  5. In high risk patients, and those known to have adverse cytogenetics at entry, to compare novel treatment, CPX-351 vs FLAG-Ida
  6. In high risk patients who have received 2 courses of FLAG-Ida induction, to evaluate in a non randomised fashion the combination of Fludarabine + CPX-351
  7. In high risk patients, to evaluate, the value of allogeneic stem cell transplantation (SCT), from sibling or alternative donors
  8. To assess the clinical value of minimal residual disease monitoring for patients overall survival
- For patients with APL the aims of the AML19 trial are:

1. To evaluate the Idarubicin based, AIDA Schedule
2. Endpoints for Patients who have non-APL AML. The main endpoints for each comparison will be:
  - 2.1. Overall survival (OS)
  - 2.2. Complete remission (CR) achievement and reasons for failure (for induction questions)
  - 2.3. Duration of remission, relapse rates and deaths in first CR
  - 2.4. Toxicity, both haematological and non-haematological
  - 2.5. Quality of life for patients in the disease monitoring randomisation
  - 2.6. Supportive care requirements (and other aspects of health economics)

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Wales REC 3, 12/08/2014, ref. 14/WA/1056

### **Study design**

Randomized controlled open-label phase III trial, factorial design

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Acute myeloid leukaemia and myelodysplastic syndrome

### **Interventions**

Current interventions as of 25/02/2021:

Patients with CD33 positive de novo AML are randomised in a 1:1 ratio between DA chemotherapy and one dose of Mylotarg (given at a dose of 3 mg/m<sup>2</sup> on Day 1 of Course 1), and DA chemotherapy and two doses of Mylotarg (given at a dose of 3 mg/m<sup>2</sup> up to maximum of 5 mg, on Day 1 and Day 4 of course 1).

Patients who have a FLT3 mutation identified by the AML19 laboratory will have Midostaurin added to their treatment regimen, at a dose of 50 mg PO twice daily (Days 11-24 of Course 1).

All patients have DA chemotherapy alone in Course 2, and receive high dose Ara-C as consolidation treatment in Courses 3 and 4.

Those who receive Midostaurin will take this on Days 9-22 of Course 1, and Days 8-21 of Courses 3 and 4. Patients on Midostaurin will then have Midostaurin maintenance therapy for 12 cycles of 28 days.

If a patient is identified to be high-risk at any time, they should be taken off-trial and FLAG-Ida /transplant is recommended.

Previous interventions:

The AML19 trial looks to build upon previous trials in AML. It is known that the condition can present with one of two subtypes, and this is taken into account in the trial design.

In the majority of patients (those who do not have the APL-subtype), the trial looks to refine the current standard of care (which is a combination of drugs called DA) by asking a number of questions:

1. To compare two drug combinations (Daunorubicin/Ara-C DA vs Fludarabine/Ara-C/G-CSF /Idarubicin FLAG-Ida) to see which gives better survival
2. To identify the best way of giving the drug Mylotarg in addition to chemotherapy either at a single dose of 3mg/m<sup>2</sup> or in 2 doses of either 3mg/m<sup>2</sup> or 5mg whichever is smaller. (This randomisation will only be available to patients who are suitable to receive Mylotarg).
3. In patients who receive FLAG-Ida, to work out the optimal number of courses of treatment. In particular, how much if any consolidation treatment with Ara-C is required a randomisation between 0,1 and 2 courses of consolidation
4. To see if inhibiting a protein called HSP-90 with a drug called Ganetespib will improve outcomes
5. For poor risk patients, to see if a new drug called CPX-351 is any better than standard of care, which is FLAG-Ida
6. In patients who fail following 2 courses of FLAG-Ida (and so would not be suitable for further FLAG-Ida treatment) to evaluate a combination of Fludarabine and CPX-351
7. To evaluate whether a stem-cell transplant (e.g a bone marrow transplant) from either a matched sibling or unrelated donor can improve outcomes
8. To see whether monitoring patients bone marrow and blood sequentially can improve outcomes by successfully predicting patients who are likely to relapse, and what effect this has on quality of life.

Additionally patients who are found to have a FLT-3 mutation will be able to access the AML19 Pilot Trial of Ponatinib.

In patients with the APL subtype we will continue to assess the real-world effectiveness of standard of care, which is a combination of drugs called AIDA (ATRA plus Idarubicin), and to allow patients to access residual disease monitoring.

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Gemtuzumab ozogamicin, daunorubicin, cytarabine, midostaurin

## **Primary outcome(s)**

Current primary outcome measure as of 25/02/2021:

Overall survival in patient groups of differing risk status by measuring time from randomisation into particular arms of the study until death from any cause

Previous primary outcome measure:

To be assessed at the end of trial.

The AML19 trial looks to build upon previous trials in AML. It is known that the condition can present with one of two subtypes, and this is taken into account in the trial design. In the majority of patients (those who do not have the APL-subtype), the trial looks to refine the current standard of care (which is a combination of drugs called DA) by asking a number of questions:

1. To compare two drug combinations (Daunorubicin/Ara-C DA vs Fludarabine/Ara-C/G-CSF

/Idarubicin FLAG-Ida) to see which gives better survival

2. To identify the best way of giving the drug Mylotarg in addition to chemotherapy either at a single dose of 3mg/m<sup>2</sup> or in 2 doses of either 3mg/m<sup>2</sup> or 5mg whichever is smaller. (This randomisation will only be available to patients who are suitable to receive Mylotarg).
3. In patients who receive FLAG-Ida, to work out the optimal number of courses of treatment. In particular, how much if any consolidation treatment with Ara-C is required a randomisation between 0,1 and 2 courses of consolidation
4. To see if inhibiting a protein called HSP-90 with a drug called Ganetespib will improve outcomes
5. For poor risk patients, to see if a new drug called CPX-351 is any better than standard of care, which is FLAG-Ida
6. In patients who fail following 2 courses of FLAG-Ida (and so would not be suitable for further FLAG-Ida treatment) to evaluate a combination of Fludarabine and CPX-351
7. To evaluate whether a stem-cell transplant (e.g a bone marrow transplant) from either a matched sibling or unrelated donor can improve outcomes
8. To see whether monitoring patients bone marrow and blood sequentially can improve outcomes by successfully predicting patients who are likely to relapse, and what effect this has on quality of life.

Additionally patients who are found to have a FLT-3 mutation will be able to access the AML19 Pilot Trial of Ponatinib. In patients with the APL subtype we will continue to assess the real-world effectiveness of standard of care, which is a combination of drugs called AIDA (ATRA plus Idarubicin), and to allow patients to access residual disease monitoring.

### **Key secondary outcome(s)**

Current secondary outcome measures as of 01/03/2021:

1. Achievement of complete remission (CR) after treatment in all patient groups by measuring time from randomisation until time of first CR
2. Duration of CR by measuring time from first CR to first relapse
3. Rate of relapse by treatment group measured using number of events of relapse following CR recorded in participant notes between randomisation and the end of the study
4. Toxicities experienced in each course of treatment in all patient groups measured using number of events of toxicity recorded in participant notes between randomisation and the end of the study
5. Safety and efficacy of Midostaurin in patients with a FLT3 mutation who have received DA chemotherapy combined with Gemtuzumab Ozogamicin (Mylotarg) measured using number of adverse events recorded in participant notes between randomisation and the end of the study and overall survival from randomisation until death from any cause
6. Quality of life in all patient groups measured using the EORTC QLQ-C30 Version 3 questionnaire at baseline, prior to C2 (~6 weeks), 3, 6, 9, and 12 months after randomisation

Previous secondary outcome measures as of 25/02/2021:

1. Achievement of complete remission (CR) after treatment in all patient groups by measuring time from randomisation until time of first CR
2. Duration of CR by measuring time from first CR to first relapse
3. Rate of relapse by treatment group measured using number of events of relapse following CR recorded in participant notes between randomisation and the end of the study
4. Toxicities experienced in each course of treatment in all patient groups measured using number of events of toxicity recorded in participant notes between randomisation and the end of the study
5. Safety and efficacy of Midostaurin in patients with a FLT3 mutation who have received DA chemotherapy combined with Gemtuzumab Ozogamicin (Mylotarg) measured using number of

adverse events recorded in participant notes between randomisation and the end of the study and overall survival from randomisation until death from any cause

## 6. Quality of life in all patient groups

Previous secondary outcome measures:

To be reviewed at the end of the trial.

In addition to the main clinical questions above, the trial will collect a lot of data on a well characterised group of patients. This will enable the following questions to be addressed:

1. What is the relevance of detecting minimal residual disease using one of two methods (molecular and immunophenotypic)
2. Are there biomarkers or other molecular (laboratory) measurements that correlate with clinical outcome

Consent will be taken to store any excess diagnostic material for future research that will inform future trials.

## Completion date

31/07/2023

## Eligibility

### Key inclusion criteria

Current participant inclusion criteria as of 25/02/2021:

1. One of the forms of CD33 positive (any level), favourable, standard risk or unknown cytogenetics de novo AML as defined by the WHO Classification
2. WHO performance status 0-2
3. Considered suitable for intensive chemotherapy
4. Aged 16 to 60 years with the following caveats:
  - 4.1. If intensive therapy is considered a suitable option those aged >60 years are eligible
  - 4.2. To receive midostaurin: aged  $\geq 18$  years
5. A negative pregnancy test within 2 weeks prior to trial entry in WOCBP to be repeated throughout the trial prior to each course of protocol treatment
6. Sexually active participants must agree to use an adequate and medically accepted method of contraception throughout the study, and for 6 months following treatment (female participants receiving Mylotarg should continue for 7 months following treatment), if they, or their sexual partners, are women of childbearing potential (WOCBP)
7. Written informed consent provided
8. Patients must have Serum Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST)  $\leq 2.5 \times$  upper limit of normal (ULN) and bilirubin  $\leq 2 \times$  ULN
9. To receive midostaurin: FLT3-TKD or FLT3-ITD mutation detected by the central laboratory in Cardiff

Previous participant inclusion criteria:

AML Patients:

1. They have one of the forms of acute myeloid leukaemia as defined by the WHO Classification (Appendix A) this can be any type of de novo or secondary AML or high risk Myelodysplastic Syndrome (defined as >10% bone marrow blasts)
2. Patients with acute promyelocytic leukaemia (APL) are eligible and should be entered into the randomisations specifically for APL (see Section 9)
3. They are considered suitable for intensive chemotherapy
4. They should normally be 18 years up to the age of 60, but patients over this age are eligible if = intensive therapy is considered a suitable option

5. The serum creatinine should be  $\leq 1.5 \times \text{ULN}$  (upper limit of normal)
6. Patients eligible for the Mylotarg randomisation must have Serum Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST)  $\leq 2.5 \times \text{ULN}$  and bilirubin  $\leq 2. \times \text{ULN}$  (Note: Patients who do not comply with the liver inclusion criteria are eligible to enter the trial but will be excluded from the Mylotarg randomisation)
7. Sexually mature males must agree to use an adequate and medically accepted method of contraception throughout the study if their sexual partners are women of child bearing potential (WOCBP). Similarly women must agree to adequate contraceptive measures. This applies to APL and AML patients. In both males and females these measures must be in place for at least 30 days after the last administration of ganetespib
8. They have given written informed consent

**APL Patients:**

1. They have provided signed written informed consent (PIS 3)
2. They have a morphological diagnosis of APL (if cytogenetic or molecular diagnosis is not confirmed patients will transfer to the non-APL treatments)
3. They should be over 18 years
4. They have WHO performance status 0-2
5. Their serum total bilirubin is  $< 2.0 \text{ mg/dL}$  ( $\leq 51 \mu\text{mol/L}$ )
6. Their serum creatinine is  $< 3.0 \text{ mg/dL}$  ( $< 260 \mu\text{mol/L}$ )

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

16 years

**Upper age limit**

60 years

**Sex**

All

**Total final enrolment**

1033

**Key exclusion criteria**

Current participant exclusion criteria as of 25/02/2021:

1. Patients with APL, secondary AML, therapy-related AML, high-risk myelodysplastic syndrome with  $< 20\%$  bone marrow blasts, or de novo AML with known adverse risk cytogenetics
2. Patients who have previously received cytotoxic chemotherapy for AML. Hydroxycarbamide, or similar low-dose therapy, to control the white count prior to initiation of intensive therapy is not an exclusion.
3. Blast transformation of chronic myeloid leukaemia (CML)
4. Concurrent active malignancy requiring treatment
5. Pregnant or lactating

Previous participant exclusion criteria:

Patients are not eligible for the AML arms of the AML19 trial if:

1. They have previously received cytotoxic chemotherapy for AML. [Hydroxycarbamide, or similar low-dose therapy, to control the white count prior to initiation of intensive therapy is not an exclusion.]
2. They have received demethylation therapy for AML or high risk MDS defined as marrow blasts >10%. Patients treated for lower risk MDS who progress to AML are eligible
3. They are in blast transformation of chronic myeloid leukaemia (CML)
4. They have a concurrent active malignancy requiring treatment
5. They are pregnant or lactating
6. The physician and patient consider that intensive therapy is not an appropriate treatment option
7. Known infection with Human Immunodeficiency Virus (HIV)
8. Patients with AST or ALT more than 2.5 times the local upper limit of normal or Bilirubin more than twice upper limit of normal, are not eligible for the Mylotarg randomisations

For Ganetespib randomisation there are specific cardiac exclusions:

1. A myocardial infarction within 12 months
2. Uncontrolled angina within 6 months
3. Current or history of congestive heart failure New York Heart Association (NYHA) class 3 or 4, unless an echocardiogram (ECHO) or Multiple Gated Acquisition Scan (MUGA) performed either within 1 month prior to study screening or during screening results in a left ventricular ejection fraction (LVEF) that is  $\geq 45\%$  (or institutional lower limit of normal value)
4. Diagnosed or suspected congenital long QT syndrome. Any history of clinically significant ventricular arrhythmias (such as ventricular tachycardia, ventricular fibrillation, torsades de pointes [TdP]) or any history of arrhythmia will be discussed with the Clinical Coordinator/Safety Physician prior to patients entry into the study
5. Prolonged QTcF interval on pre-entry ECG ( $\geq 450$  ms)
6. Any history of second or third degree heart block (may be eligible if the patient currently has a pacemaker)
7. Heart rate <50/minute on pre-entry ECG
8. Uncontrolled hypertension
9. Obligate need for a cardiac pacemaker
10. Complete left bundle branch block
11. Atrial fibrillation

APL Patients:

1. They are aged < 18
2. They have an active malignancy requiring treatment at time of study entry
3. There is a lack of subsequent diagnostic confirmation of PML-RARA fusion at molecular level
4. Known infection with Human Immunodeficiency Virus (HIV)
5. Significant arrhythmias, ECG abnormalities or neuropathy are apparent
6. Severe uncontrolled pulmonary or cardiac disease is apparent
7. They are pregnant or lactating

**Date of first enrolment**

01/01/2015

**Date of final enrolment**

29/10/2021

**Locations**

**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

Denmark

New Zealand

**Study participating centre**

**Nottingham University**

Nottingham

United Kingdom

NG5 1PB

**Study participating centre**

**Aalborg University Hospital**

Dept. of Haematology

Clinical Trial Unit

Moelleparkvej 4

Aalborg

Denmark

DK-9000

**Study participating centre**

**Aarhus University Hospital**

Tage-Hansens Gade 2

Aarhus

Denmark

8000

**Study participating centre**

**Aberdeen Royal Infirmary**

Haematology Day Unit

Ward 307

Foreseter Hill

Aberdeen

United Kingdom  
AB25 2ZN

**Study participating centre**  
**Addenbrookes University Hospital**  
Addenbrookes Hospital  
Cambridge University Hospitals NHS Foundation  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**  
**Aintree University Hospital**  
Aintree Hospital  
Lower Lane  
Liverpool  
United Kingdom  
L9 7AL

**Study participating centre**  
**Arrowe Park Hospital**  
Arrowe Park Road  
Upton  
Wirral  
United Kingdom  
CH49 5PE

**Study participating centre**  
**Auckland Hospital**  
2 Park Road  
Grafton  
Auckland  
New Zealand  
1023

**Study participating centre**  
**Basingstoke and North Hampshire Hospital**  
Aldermaston Road

Basingstoke  
United Kingdom  
RG24 9NA

**Study participating centre**

**Beatson WOS Cancer Centre**

Cancer Research UK Clinical Trials Unit  
West of Scotland Beatson Cancer Centre, Level 0  
1053 Great Western Road  
Glasgow  
United Kingdom  
G12 0YN

**Study participating centre**

**Belfast City Hospital**

51 Lisburn Road  
Belfast  
United Kingdom  
BT9 7AB

**Study participating centre**

**Birmingham Heartlands Hospital**

Bordesley Green East  
Birmingham  
United Kingdom  
B9 5SS

**Study participating centre**

**Blackpool Victoria Infirmary**

Blackpool Victoria Hospital  
Whinney Heys Road  
Blackpool  
United Kingdom  
FY3 8NR

**Study participating centre**

**Bradford Royal Infirmary**

Duckworth Lane  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**  
**Bristol Haematology and Oncology Centre**  
Horfield Road  
Bristol  
United Kingdom  
BS2 8ED

**Study participating centre**  
**Castle Hill Hospital**  
Queens Centre for Oncology & Haematology  
Castle Road  
Cottingham  
United Kingdom  
HU16 5JQ

**Study participating centre**  
**Cheltenham General Hospital**  
Sandford Road  
Cheltenham  
United Kingdom  
GL53 7AN

**Study participating centre**  
**Chesterfield Royal Hospital**  
Calow  
Chesterfield  
United Kingdom  
S44 5BL

**Study participating centre**  
**Christchurch Hospital**  
Riccarton Road  
Christchurch  
New Zealand  
8011

**Study participating centre**

**The Christie Haematology and Transplant Unit**

Wilmslow Road  
Withington  
Manchester  
United Kingdom  
M20 4BX

**Study participating centre**

**Churchill Hospital**

Cancer and Haematology Centre  
Level 2  
Old Road  
Headington  
Oxford  
United Kingdom  
OX3 9EP

**Study participating centre**

**Clatterbridge Cancer Centre**

The Royal Liverpool Hospital  
Clatterbridge Road  
Bebington  
Wirral  
United Kingdom  
CH63 4JY

**Study participating centre**

**Conquest Hospital**

Sussex Cancer Research Team  
St Anne's House  
729 The Ridge  
East Sussex  
United Kingdom  
TN37 7PT

**Study participating centre**

**Countess of Chester Hospital**

Liverpool Road  
Chester  
Cheshire  
United Kingdom  
CH2 1UL

**Study participating centre**  
**Croydon University Hospital**  
Research Office  
1st Floor Woodcroft Wing  
London Road  
Croydon  
United Kingdom  
CR7 7YE

**Study participating centre**  
**Derriford Hospital**  
Derriford Road  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**  
**Doncaster Hospital**  
Doncaster & Bassetlaw Hospitals NHS Foundation Trust  
Armthorpe Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**  
**Dunedin Hospital**  
Dunedin Hospital  
Southern Blood and Cancer Service  
201 Great King Street  
Dunedin  
New Zealand  
9016

**Study participating centre**  
**Eastbourne District General Hospital**  
Kings Drive  
Eastbourne  
United Kingdom  
BN21 2UD

**Study participating centre**  
**Forth Valley Royal Hospital**  
Oncology Department  
Stirling Road  
Larbet  
United Kingdom  
FK5 4WR

**Study participating centre**  
**Freeman Hospital**  
Haematology Research  
Level 2 NCCC  
Newcastle upon Tyne Hospitals NHS Foundation Trust  
Newcastle Upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**Glan Clwyd Hospital**  
Bodelwyddan  
Denbighshire  
United Kingdom  
LL18 5UJ

**Study participating centre**  
**Gloucestershire Royal Hospital**  
Great Western Road  
Gloucester  
United Kingdom  
GL1 3NN

**Study participating centre**  
**Guy's Hospital**  
Guy's and St Thomas NHS Trust  
Great Maze Pond  
Clinical Haematology  
4th Floor Southwark Wing  
London  
United Kingdom  
SE1 9RT

**Study participating centre**  
**Herlev and Gentofte Hospital**  
Herlev Ringvej 75  
Herlev  
Denmark  
2730

**Study participating centre**  
**Hillingdon Hospital**  
Pield Heath Road  
Uxbridge  
United Kingdom  
UB8 3NN

**Study participating centre**  
**Ipswich Hospital**  
Heath Road  
Ipswich  
United Kingdom  
IP4 5PD

**Study participating centre**  
**James Cook University Hospital**  
NIHR- Clinical Research Network North East and Cumbria  
Department of Radiotherapy and Oncology  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**  
**James Paget Hospital**  
Lowestoft Road  
Gorleston-on-Sea  
Great Yarmouth  
Norfolk  
United Kingdom  
NR31 6LA

**Study participating centre**

**Kettering General Hospital**  
Rothwell Road  
Kettering  
United Kingdom  
NN16 8U2

**Study participating centre**  
**Leicester Royal Infirmary**  
The Hope Clinical Trials Unit  
Level 2 Osborne Building  
Infirmary Square  
Leicester  
United Kingdom  
LE1 SWW

**Study participating centre**  
**Lewisham**  
Lewisham High St  
London  
United Kingdom  
SE13 6LH

**Study participating centre**  
**Lincoln County Hospital**  
Greetwell Road  
Lincoln  
United Kingdom  
LN2 5QY

**Study participating centre**  
**Manchester Royal Infirmary**  
Oxford Road  
Manchester  
United Kingdom  
M13 9W

**Study participating centre**  
**Medway Maritime Hospital**  
Windmill Road

Gillingham  
United Kingdom  
ME7 5NY

**Study participating centre**  
**Milton Keynes Hospital**  
Standing Way  
Eaglestone  
Milton Keynes  
United Kingdom  
MK6 5LD

**Study participating centre**  
**Monklands Hospital**  
Monkscourt Ave  
Airdrie  
United Kingdom  
ML6 0JS

**Study participating centre**  
**Musgrove Park Hospital**  
Parkfield Drive  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**  
**New Cross Hospital**  
Wednesfield Road  
Wolverhampton  
United Kingdom  
WV10 0QP

**Study participating centre**  
**New Victoria Hospital**  
The New Victoria Ach  
Grange Road  
Glasgow  
United Kingdom  
G42 9LF

**Study participating centre**  
**Ninewells Hospital and Medical Centre**  
James Arrott Drive  
Dundee  
United Kingdom  
DD1 9SY

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

**Study participating centre**  
**Northampton General Hospital**  
Haematology Day Unit  
Cliftonville  
Northampton  
United Kingdom  
NN1 5BD

**Study participating centre**  
**Centre for Clinical Haematology**  
Nottingham University Hospitals NHS Trust  
City Hospital Campus  
Hucknall Road  
Nottingham  
United Kingdom  
NG5 1PB

**Study participating centre**  
**Odense University Hospital**  
Hæmatologisk Forskningeenhed HFE-X  
Klørvænget 10,12 sal  
Odense  
Denmark  
5000

**Study participating centre**  
**Palmerston North Hospital**  
Regional Cancer Treatment Service  
Department of Clinical Haematology  
Private Bag 11036  
Manawatu Mail Centre  
Palmerston North  
New Zealand  
4442

**Study participating centre**  
**Pinderfields General Hospital**  
Research Team  
Rowan House  
Aberford Road  
Wakefield  
United Kingdom  
WF1 4DG

**Study participating centre**  
**Poole Hospital**  
Poole Hospital NHS Trust  
Longfleet Road  
Poole  
United Kingdom  
BH15 2JB

**Study participating centre**  
**Queen Alexandra Hospital**  
Haematology and Oncology Research  
Cosham  
Portsmouth  
United Kingdom  
P06 3LY

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

**Study participating centre**  
**Queen Elizabeth Hospital**  
Stadium Road  
London  
United Kingdom  
SE18 4QH

**Study participating centre**  
**Queens Hospital**  
9 Cancer Clinical Trials Unit  
Rom Valley Way  
Romford  
United Kingdom  
RM7 0AG

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

**Study participating centre**  
**Rigshospitalet**  
Blegdamsvej  
Clinical Trial Team (KAT)- 4042  
Copenhagen  
Denmark  
2100

**Study participating centre**  
**Roskilde Sygehus**  
Hæmatologisk Afdeling  
Klinisk Forskningsenhed  
Indgang 27 A, 1. Sl  
Roskilde  
Denmark  
4000

**Study participating centre**

**Rotherham General Hospital**

Moorgate Road  
Rotherham  
United Kingdom  
S60 2UD

**Study participating centre**

**Royal Berkshire Hospital**

London Road  
Reading  
United Kingdom  
RG1 5AN

**Study participating centre**

**Royal Bournemouth Hospital**

Castle Lane East  
Bournemouth  
United Kingdom  
BH77DW

**Study participating centre**

**Royal Cornwall Hospital**

Haematology department  
Treliske  
Truro  
United Kingdom  
TR1 3LJ

**Study participating centre**

**Royal Derby Hospital**

Uttoxeter Road,  
Derby  
United Kingdom  
DE22 3NE

**Study participating centre**

**Royal Devon and Exeter Hospital**

Royal Devon & Exeter Road  
Barrack Road

Exeter  
United Kingdom  
EX2 5DW

**Study participating centre**  
**Royal Hallamshire Hospital**  
Glossop Road  
Sheffield  
United Kingdom  
S10 2JF

**Study participating centre**  
**Royal Marsden Hospital**  
The Royal Marsden NHS Foundation Trust  
Downs Road  
Sutton  
United Kingdom  
SM2 5PT

**Study participating centre**  
**Royal Oldham Hospital**  
Marjorie Lees Unit, Room 31  
Rochdale Road  
Oldham  
United Kingdom  
OL1 2JH

**Study participating centre**  
**Royal Stoke University Hospital**  
Newcastle Road  
Stoke-on-Trent  
United Kingdom  
ST4 6QG

**Study participating centre**  
**Royal Surrey County Hospital**  
St Lukes Cancer Centre  
Royal Surrey County Hospital NHS Foundation Trust  
Egerton Road

Guildford  
United Kingdom  
GU2 7XX

**Study participating centre**

**Royal United Hospitals**

Royal United Hospitals NHS Foundation Trust  
Dept A14  
Combe Park  
Bath  
United Kingdom  
BA1 3NG

**Study participating centre**

**Russells Hall Hospital**

Pensnett Road  
Dudley  
United Kingdom  
DY1 2HQ

**Study participating centre**

**Salford Royal Hospital**

Oncology Research Department  
Summerfield House  
Salford Royal NHS Foundation Trust  
Stott Lane  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**

**Salisbury District Hospital**

Haematology Department, Pathology  
Salisbury NHS Foundation Trust  
Salisbury  
United Kingdom  
SP2 8BJ

**Study participating centre**

**Sandwell Hospital**

Lyndon

West Bromwich  
United Kingdom  
B71 4HJ

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

**Study participating centre**  
**Southampton General Hospital**  
University Hospital Southampton NHS Foundation Trust  
Tremona Road  
Southampton  
United Kingdom  
S016 6YD

**Study participating centre**  
**St Bartholomew's Hospital**  
West Smithfield  
London  
United Kingdom  
EC1A 7BE

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

**Study participating centre**  
**St Helens Hospital**  
St Helens and Knowsley NHS Trust  
Warrington Road  
Prescot  
Merseyside  
United Kingdom  
L35 5DR

**Study participating centre**  
**St James University Hospital**  
Level 3 Bexley Wing  
Becket Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre**  
**St Richard's Hospital**  
Spitalfield Lane  
Chichester  
United Kingdom  
PO19 6SE

**Study participating centre**  
**Stoke Mandeville Hospital**  
Mandeville Road  
Aylesbury  
United Kingdom  
HP21 8AL

**Study participating centre**  
**Sunderland Royal Hospital**  
Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**Torbay District General Hospital**  
Lawes Bridge  
Torquay  
United Kingdom  
TQ2 7AA

**Study participating centre**

**University College London Hospitals**

Haematology CCTU

1st Floor Central

250 Euston Road,

London

United Kingdom

NW1 2PG

**Study participating centre**

**University Hospital Ayr**

Dalmellington Road

Ayr

United Kingdom

KA6 6DX

**Study participating centre**

**University Hospital Coventry**

Clifford Bridge Road

Coventry

United Kingdom

CV2 2DX

**Study participating centre**

**University Hospital Crosshouse**

Kilmarnock Road

Crosshouse

Kilmarnock

United Kingdom

KA2 0BE

**Study participating centre**

**University Hospital of Wales**

Heath Park

Cardiff

United Kingdom

CF14 4XW

**Study participating centre**

**Victoria Hospital**

Hayfield Road

Kirkcaldy

Fife  
United Kingdom  
KY2 5AH

**Study participating centre**

**Waikato Hospital**

Waikato District Health Board  
Pembroke Street  
Private Bag 3200  
Hamilton  
New Zealand  
3240

**Study participating centre**

**Western General Hospital**

Haematology Department  
Crewe Road South  
Edinburgh  
United Kingdom  
EH4 2XU

**Study participating centre**

**Worcestershire Royal Hospital**

Charles Hastings Way  
Worcester  
United Kingdom  
WR5 1DD

**Study participating centre**

**Worthing Hospital**

Lyndhurst Road  
Worthing  
United Kingdom  
BN11 2DH

**Study participating centre**

**Wycombe Hospital**

Queen Alexandra Road  
High Wycombe  
United Kingdom  
HP11 2TT

**Study participating centre****York Hospital**

Cancer Research Team, Research, and Development

Learning and Research Centre (LARC)

Wigginton Road

York

United Kingdom

YO31 8HE

**Study participating centre****Ysbyty Gwynedd**

Penrhosgarnedd

Bangor

United Kingdom

LL57 2PW

**Sponsor information****Organisation**

Cardiff University (UK)

**ROR**

<https://ror.org/03kk7td41>

**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

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		12/05/2023	15/05/2023	Yes	No
<a href="#">Results article</a>		12/01/2024	15/01/2024	Yes	No
<a href="#">Results article</a>		01/05/2025	01/05/2025	Yes	No
<a href="#">Results article</a>		30/09/2025	01/10/2025	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes