ISRCTN78449203 https://doi.org/10.1186/ISRCTN78449203

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

| | | |
|---|---|---|
| **Submission date**<br>30/09/2014 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>08/12/2014 | **Overall study status**<br>Completed | |
| **Last Edited**<br>01/05/2025 | **Condition category**<br>Cancer | |

**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

**Study website**
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/aml19

## 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

**EudraCT/CTIS number**
2014-002195-90

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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/m2) or DA + Mylotarg (3mg/m2 x2, maximum 5mg per day)versus FLAG-Ida + Mylotarg (3mg/m2) or FLAG-Ida + Mylotarg (3mg/m2 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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Patient information sheets are provided through the patients hospital setting

## 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/m² on Day 1 of Course 1), and DA chemotherapy and two doses of Mylotarg (given at a dose of 3 mg/m² 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 recieve high dose Ara-C as consolidation treatment in Courses 3 and 4.

Those who recieve 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/m2 or in 2 doses of either 3mg/m2 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 his 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 measure

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/m2 or in 2 doses of either 3mg/m2 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 his 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.

## Secondary outcome measures

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.

### Overall study start date
01/01/2015

### 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 theWHO 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 ≥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) ≤2.5 × upper limit of normal (ULN) and bilirubin ≤2 × 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 ≤ 1.5 × ULN (upper limit of normal)
6. Patients eligible for the Mylotarg randomisation must have Serum Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST) ≤2.5 × ULN and bilirubin ≤2.× 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 mg/dL (≤51 µmol/L)
6. Their serum creatinine is < 3.0 mg/dL (< 260 µmol/L)

## Participant type(s)
Patient

## Age group
Adult

## Lower age limit
16 Years

## Upper age limit
60 Years

## Sex
Both

## Target number of participants
2150 (1888 patients recruited prior to the COVID-19 pandemic, 250 to be recruited under the new protocol)

## 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 ≥ 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 (≥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
Denmark

England

New Zealand

Northern Ireland

Scotland

United Kingdom

Wales

### 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**
Haemotology 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
Mancester
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
Kløvervænget 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 Hosptial**
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 Hosptial**
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)

**Sponsor details**
Research, Innovation & Enterprise Services, 7th Floor, 30-36 Newport Road
Cardiff
Wales
United Kingdom
CF10 3XQ
-
resgov@cardiff.ac.uk

**Sponsor type**

University/education

**ROR**
https://ror.org/03kk7td41

# 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

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 12/05/2023 | 15/05/2023 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Results article | | 12/01/2024 | 15/01/2024 | Yes | No |
| Results article | | 01/05/2025 | 01/05/2025 | Yes | No |