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

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

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Type(s)
Scientific

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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
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Study participating centre
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United Kingdom
B71 4HJ

Study participating centre
Singleton Hospital
Sketty Lane
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SA2 8QA

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

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

Study participating centre
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Blackshaw Road
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United Kingdom
SW17 0QT

Study participating centre
St Helens Hospital
St Helens and Knowsley NHS Trust
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United Kingdom
L35 5DR

Study participating centre
St James University Hospital
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Becket Street
Leeds
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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
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HP21 8AL

Study participating centre
Sunderland Royal Hospital
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United Kingdom
SR4 7TP

Study participating centre
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TQ2 7AA

Study participating centre
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NW1 2PG

Study participating centre
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United Kingdom
KA6 6DX

Study participating centre
University Hospital Coventry
Clifford Bridge Road
Coventry
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CV2 2DX

Study participating centre
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Crosshouse
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United Kingdom
KA2 0BE

Study participating centre

University Hospital of Wales
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CF14 4XW

Study participating centre
Victoria Hospital
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Fife
United Kingdom
KY2 5AH

Study participating centre
Waikato Hospital
Waikato District Health Board
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Private Bag 3200
Hamilton
New Zealand
3240

Study participating centre
Western General Hospital
Haematology Department
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Edinburgh
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Study participating centre
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United Kingdom
WR5 1DD

Study participating centre
Worthing Hospital
Lyndhurst Road

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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)
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YO31 8HE

Study participating centre
Ysbyty Gwynedd
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LL57 2PW

Sponsor information

Organisation
Cardiff University (UK)

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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