







A trial of directed therapy in younger patients with acute myeloid leukaemia: MRC AML 15

Submission date 02/05/2001	Recruitment status No longer recruiting	 Prospectively registered
		 Protocol not yet added
Registration date 02/05/2001	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 24/03/2022	Condition category Cancer	 Raw data not yet added
		 Study completed

Plain English Summary

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-comparing-different-chemotherapy-regimes-and-the-use-of-mylotarg-monoclonal-antibody-in-treatment-of-acute-myeloid-leukaemia>

Study website

<http://www.aml15.bham.ac.uk/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

2005-001149-40

IRAS number

ClinicalTrials.gov number

Protocol/serial number

G9901427

Study information

Scientific Title

A trial of directed therapy in younger patients with acute myeloid leukaemia: MRC AML 15

Acronym

MRC AML 15

Study hypothesis

The AML trial has two separate parts:

1. For patients with Acute Myeloid Leukaemia (AML), other than acute promyelocytic leukaemia (APL), as defined by the World Health Organisation (WHO) classification (2001).
2. For patients with Acute Promyelocytic Leukaemia (APL).

The objectives for each of these components are summarised below.

Therapeutic questions for patients with non-APL AML: For patients with acute myeloid leukaemia (AML) the aims of the AML15 trial are:

1. To compare two induction schedules (namely DAT and FLAG-Ida)
2. To assess the value of Mylotarg during induction
3. To compare the standard MRC consolidation chemotherapy (i.e. MACE + MidAC) versus high-dose Ara-C
4. For those allocated to high-dose Ara-C to compare high-dose ARA-C during consolidation (see above) at two different doses (1.5 g/m squared versus 3.0g/m squared)
5. To assess the value of Mylotarg during consolidation
6. To compare four versus five courses of treatment in total (where the final course is intermediate-dose Ara-C)
7. In standard and poor risk patients, to evaluate, by means of a genetic randomisation, the value of allogeneic stem cell transplantation [SCT, whether standard allogeneic (allo-SCT) or non-myeloablative mini allogeneic (mini-SCT)]

Therapeutic questions for patients with APL. For patients with APL:

1. To compare the MRC approach (i.e. four courses of intensive chemotherapy) with the Spanish approach (based on anthracyclines with maintenance therapy)
2. To assess the value of Mylotarg during consolidation (i.e. with course 3)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Condition

Leukaemia

Interventions

1. (R1) Patients with acute promyelocytic leukemia (APL) will be randomised to receive oral retinoic acid together with either MRC H-DAT chemotherapy or the Spanish Intermittent Idarubicin. Following confirmation of remission, patients will continue with the MRC (DAT:MACE: MIDAC) or Spanish chemotherapy but will be randomised to receive CMA-676/Myelotarg (Immunoconjugate) on day 1 of course 3 or not. (Patients will be monitored molecularly by Reverse Transcription (RT) and real time Polymerase Chain Reaction (PCR) to predict relapse. Three quality of life assessments will be made at 3, 6 and 9 months and resource use information will be collected for cost benefit analysis.)
2. (R2) Non-APL patients will be randomised to receive induction courses 1 and 2 with H-Dat (Daunorubicin:Ara-C, Thioguanine) or FLA_G IDA (Fludarabine, Ara C, G-CSF, Idarubicin) and to receive CMA-676 (Myelotarg) on day 1 of course 1 or not.
3. Following the first course of chemotherapy the risk profile of each patient will be determined (based on cytogenetics, blast clearance after course 1). Good risk patients (15%) will leave AML15 and will enter the MRC AML High Risk Trial.
4. (R3)(R4) Patients who have completed course 2 and are allocated to the chemotherapy comparisons will be randomised to receive CMA-676 (Myelotarg) on day 1 of course 3.
5. (R5) All patients allocated to allogeneic transplant up to 35 years will receive standard conditioning (Cyclophosphamide/TBI) with stem cells obtained from peripheral blood or bone marrow as course 3. For patients 36-50 investigators may choose a conventional transplant or a non-ablative transplant. Patients over 50 years will receive a non-ablative transplant. The non-ablative transplant will be given as course 4, ie patients will receive MACE as course 3 before proceeding to transplant.
7. Patients who relapse at any point in the trial will be entered into the MRC AML HR Trial.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The main endpoints for each comparison will be:

1. Complete remission (CR) achievement and reasons for failure (for induction questions)

2. Duration of remission, relapse rates and deaths in first CR
3. Overall survival
4. Toxicity, both haematological and non-haematological, and quality of life
5. Supportive care requirements (and other aspects of health economics)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2002

Overall study end date

01/06/2008

Eligibility

Participant inclusion criteria

1. Any form of de novo or secondary AML
2. Suitable for intensive chemotherapy
3. Under 60 years
4. Written consent

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

3000

Participant exclusion criteria

1. Previous chemotherapy for AML
2. Blast transferration of CML
3. Pregnant or lactating
4. Abnormal liver function tests for Mylotarg randomisations

Recruitment start date

01/03/2002

Recruitment end date

01/06/2008

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre
Department of Haematology
Cardiff
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CF14 4XN

Sponsor information

Organisation
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Sponsor details

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Sponsor type
University/education

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

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype

National government

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	results of a feasibility study	15/12/2003		Yes	No
Results article	results	04/02/2010		Yes	No
Other publications	pooled analysis of prognostic significance of rare recurring chromosomal abnormalities	22/07/2010		Yes	No
Results article	results	04/10/2012		Yes	No
Results article	results	01/04/2013		Yes	No
Results article	results	20/09/2013		Yes	No
Results article	results	10/07/2014		Yes	No
Results article	results	01/01/2018	25/07/2019	Yes	No
Plain English results		23/08/2013	29/10/2021	No	Yes
Plain English results			24/03/2022	No	Yes