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AML17: a programme of treatment development in younger patients with Acute Myeloid Leukaemia and high-risk myelodysplastic syndrome

Submission date
21/06/2007

Recruitment status
No longer recruiting

Registration date
02/07/2007

Overall study status
Completed

Last Edited
01/05/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-treatment-children-acute-myeloid-leukaemia-aml-17
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-acute-myeloid-leukaemia-aml-17
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-treatment-acute-promyelocytic-leukaemia-AML-17

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2007-003798-16

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CU 372-07

Study information

Scientific Title
AML17: a programme of treatment development in younger patients with Acute Myeloid Leukaemia and high-risk myelodysplastic syndrome

Acronym
AML17

Study objectives
Best chemotherapy +/- molecular intervention and risk-directed chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC for Wales, 08/10/2008, ref: 08/MRE09/29

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute myeloid leukaemia/high-risk myelodysplastic syndrome

Interventions
Current interventions as of 24/06/2008:
1. In acute promyelocytic leukaemia (APL) patients to compare idarubicin and all-trans retinoic acid (ATRA) versus ATRA and arsenic
2. In non-APL patients to compare ara-C/dauno/etoposide (ADE) alone versus ADE or ara-C /dauno (DA) each with Mylotarg at two different doses (five arms):
2.1. ADE alone
2.2. ADE and Mylotarg (3 mg)
2.3. DA and Mylotarg (3 mg)
2.4. ADE and Mylotarg (6 mg)
2.5. DA and Mylotarg (6 mg)

3. Three versus four courses of total therapy
4. +/- CEP-701 (lestaurtinib) in FLT3 mutants
5. Dauno and clofarabine versus fludarabine, cytarabine, granulocyte colony-stimulating factor, and idarubicin (FLAG-Ida) in high-risk patients
6. +/- mTOR inhibition in non-CBF, non-FLT3 mutant, in non-high risk patients

The treatment period is approximately 4 to 6 months.

Previous interventions:
1. In acute promyelocytic leukaemia (APL) patients to compare idarubicin and all-trans retinoic acid (ATRA) versus ATRA and arsenic
2. In non-APL patients to compare ara-C/dauno/etoposide (ADE) alone versus ADE or ara-C /dauno (DA) each with Mylotarg at two different doses (five arms):
2.1. ADE alone
2.2. ADE and Mylotarg (3 mg)
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2.5. DA and Mylotarg (6 mg)
3. Three versus four courses of total therapy
4. +/- CEP-701 (lestaurtinib) in FLT3 mutants
5. Dauno and clofarabine versus dauno and cloretazine versus fludarabine, cytarabine, granulocyte colony-stimulating factor, and idarubicin (FLAG-Ida) in high-risk patients
6. +/- mTOR inhibition in non-CBF, non-FLT3 mutant, in non-high risk patients

The treatment period is approximately 4 to 6 months.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Idarubicin, all-trans retinoic acid (ATRA), arsenic, ara-C/dauno/etoposide (ADE), ara-C/dauno (DA), mylotarg (gemtuzumab ozogamicin), lestaurtinib, clofarabine, cloretazine, fludarabine, cytarabine, granulocyte colony-stimulating factor

Primary outcome(s)
1. Complete remission (CR), measured at approximately 1 month and if required approximately 6 weeks later i.e. after course 1 and/or 2
2. CR duration
3. Relapse rate, monitored over 5 years
4. Deaths in CR, monitored over 5 years
5. Overall survival (at 5 years)
6. Toxicity
7. Quality of life, measured at baseline and at 3, 6, 12 and 24 months for those in the APL section of the trial, and at 3, 6 and 12 months for patients in the minimal residual disease monitoring. The European Organisation for Research and Treatment of Cancer, Quality of Life Questionnaire for Cancer patients (EORTC QLQC-30) and Hospital Anxiety and Depression Score (HADS) will be used.
8. Supportive care requirements

Key secondary outcome(s))
1. Detection of minimal residual disease
2. Correlation of serum inhibitory activity

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. They have one of the forms of acute myeloid leukaemia (AML) as defined by the World Health Organization (WHO)
2. They are considered suitable for intensive chemotherapy
3. They are less than 60 years
4. For Mylotarg (gemtuzumab ozogamicin) intervention, have liver function tests within twice the upper limit of normal

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. No previous cytotoxic therapy for AML other than hydroxyurea
2. Blast transformation of chronic myeloid leukaemia (CML)
3. Concurrent active malignancy
4. Pregnant or lactating
5. Children with Down's syndrome

Date of first enrolment
01/09/2008

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
United Kingdom

Wales

Denmark

Study participating centre
Cardiff University
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Research council

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Genzyme Ltd (UK) - supplying clofarabine

Funder Name
Novartis Pharmaceuticals UK Limited (UK) - supplying mTOR inhibitor

Funder Name
Cephalon UK Ltd (UK) - providing arsenic trioxide and CEP-701

Funder Name
Bioenvision Ltd (UK) - providing clofarabine

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?
Results article	results	18/06/2015		Yes	No
Results article	results	01/10/2015		Yes	No
Results article	results	04/02/2016		Yes	No
Results article	results	01/06/2016		Yes	No
Results article	results	02/03/2017		Yes	No
Results article	results	27/02/2020	15/01/2020	Yes	No
Results article		10/03/2021	28/09/2021	Yes	No
Results article		01/05/2025	01/05/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			25/10/2022	No	Yes
Plain English results			25/10/2022	No	Yes