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TRIAL Relapsed AML 2001/01: a randomised phase III study on the treatment of children and adolescents with refractory or relapsed acute myeloid leukaemia (AML)

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
28/04/2014

Condition category
Cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR136

Study information

Scientific Title

Acronym
Relapsed AML 2001/01

Study objectives
Addition of liposomal daunorubicin (DaunoXome®) to fludarabine, ara-C and granulocyte colony-stimulating factor (G-CSF) (FLAG) in the first reinduction course will result in improved treatment response with acceptable toxicity and without increased cardiotoxicity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute myeloid leukaemia

Interventions
Addition of liposomal daunorubicin (DaunoXome®) to FLAG in reinduction course I.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Daunorubicin (DaunoXome®), fludarabine, ara-C, granulocyte colony-stimulating factor

Primary outcome(s)
Percentage of BM blasts greater than 20% after course I, determined 4 - 6 weeks after the start.

Key secondary outcome(s))
1. Toxicity, focusing on but not limited to bone marrow aplasia, mucosal toxicity and cardiotoxicity
2. Efficacy as determined by day 14 BM blasts, time to PB clearance of blasts, CR rate after two courses of chemotherapy, % of patients that underwent SCT, overall survival, event-free survival and disease-free survival

3. Clinical and cell biological features, and overall outcome of the entire cohort of patients with relapsed AML that has been registered in the time period of patient accrual (also including patients that were not treated according to this protocol)

Completion date
11/01/2007

Eligibility

Key inclusion criteria
1. Primary refractory acutye myeloid leukaemia (AML)
2. First relapsed AML
3. Second or subsequent relapsed AML, but not previously treated according to protocol Relapsed AML 2001/01
4. Below 18 years of age at initial diagnosis
5. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Symptomatic cardiac dysfunction (CTC grade 3 or 4), and/or a fractional shortening at echocardiography below 29%
2. Karnofsky performance status less than 40% (children aged 16 years and older) or Lansky performance status of less than 40% (younger children)
3. Any other organ dysfunction (CTC grade 4) that will interfere with the protocol treatment
4. Inability to apply to the protocol for other reasons
5. AML FAB type M3, acute promyelocytic leukaemia, and/or t(1517) and/or PML-RARalfa fusion gene

Date of first enrolment
11/01/2001

Date of final enrolment
11/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Pediatric Oncology/Hematology
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
Dutch Childhood Oncology Group (Stichting Kinder Oncologie [SKION]) (The Netherlands)

ROR
https://ror.org/01zs6bp63

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

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	10/02/2013		Yes	No
Results article	results	01/09/2014		Yes	No