

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	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/04/2014	Condition category Cancer	☐ 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

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

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 acute 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-RAR α 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