Prospective study of quantitative molecular minimal residual disease (MRD) monitoring in pediatric acute myeloid leukemia (AML).

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24742

Source
NTR

Brief title
QMRD in AML

Health condition

AML

Sponsors and support

Primary sponsor: Dept of Pediatric Oncology
Erasmus MC-Sophia Children's Hospital
POB 2060
3000 CB Rotterdam
Netherlands
Source(s) of monetary or material Support: Celgene

Intervention

Outcome measures

Primary outcome

Whether all newly diagnosed pediatric AML patients with specific genetic subtypes (for which a sensitive quantatative MRD marker is available) with rising MRD-values (RT-qPCR) will eventually develop relapse.

Secondary outcome

1. To study the kinetics of rising RT-qPCR levels, and the time to overt relapse, and relate this to the various genetic abnormalities, with the aim to assess the most appropriate time-interval between PB-sampling for the various genetic subcategories in pediatric AML;

2. To study MRD levels prior to SCT in patients who have relapsed and who have received standard chemotherapy re-induction for haematological relapse;

3. To set-up a network of laboratories to implement serial MRD-assessment;

4. To implement quality control between laboratories participating in this network.

Study description

Background summary

N/A

Study objective

The hypothesis is that all patients with rising RT-qPCR MRD levels of specific genetic markers in pediatric AML patients in CR1 invariably will develop overt clinical relapse.

Study design

For all patients every 4 weeks PB will be samples for MRD. Only for inv(16) patients this will be done every 8 weeks.

Intervention

Patients will be followed with monthly peripheral blood samples for quantative MRD monitoring with RT-qPCR form end of treatment in Cr1 until 18 months later or to hematological relapse.

Contacts

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Eligibility criteria

Inclusion criteria

1. AML, established according to the WHO-classification, and treated according to a collaborative group AML protocol;

2. One of the following genetic aberrations documented at diagnosis:

A. t(8;21), RUNX1-RUNX1T1;

B. inv(16), CBFb/MYH11;

C. t(9;11), MLL-AFP9;

D. t(10;11) , MLL-AFP10;

E. NPM1 mutation;

F. FLT3-ITD mutation.

3. ≤ 18 years old at initial diagnosis;

4. Life expectancy >=6 weeks;

5. A PCR target with a sensitivity of at least 10-4 needs to be available;

6. Molecular remission (< 5 x 10-4) at the end of consolidation;

7. Able to comply with scheduled follow-up;

8. Written informed consent from patients or from parents or legal guardians for minor patients, according to local law and regulations.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Down syndrome leukemia;

2. Acute promyelocytic leukemia (APL);

3. Therapy-related AML.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2012
Enrollment:	300
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3350
NTR-old	NTR3482
Other	METC Erasmus MC : 2012-01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A