

# Mylotarg as salvage treatment for children with relapsed acute myeloid leukemia.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21108

### Source

Nationaal Trial Register

### Brief title

Relapsed AML 2001/02

### Health condition

acute myeloid leukemia, AML, gemtuzumab ozogamicin, mylotarg, children, relapse

## Sponsors and support

**Primary sponsor:** VUmc, Amsterdam

**Source(s) of monetary or material Support:** Sponsor

## Intervention

## Outcome measures

### Primary outcome

Overall response rate.

### Secondary outcome

1. Adverse events;
2. All patients will be followed for time to progression and survival;
3. The number of patients that will undergo stemcell transplantation after re-induction with gemtuzumab.

## Study description

### Background summary

Summary:

Children with relapsed/refractory AML have a dire prognosis and new treatment options are urgently needed. Gemtuzumab ozogamicin is an immunoconjugate, consisting of a humanized anti-CD33 antibody, linked to calicheamicin, a cytotoxic anti-tumor antibiotic. By this approach the chemotherapy is delivered more selectively to the leukemic cells, which may increase anti-leukemic effectiveness and cause less side effects. In studies in adults response rates of approximately 30% have been reported. In a pediatric phase I study the recommended phase II dose was 7.5 mg/m<sup>2</sup> given twice with a 14-day interval.

We therefore designed an open-label phase II study with gemtuzumab ozogamicin, given as single agent at a dose of 7.5 mg/m<sup>2</sup> IV, twice with a 14-day interval, in children with refractory AML after 1st relapse and re-induction according to the Relapsed AML 2001/01 study, or children with a second relapse of AML. The main objective is to assess the complete response rate after treatment with gemtuzumab ozogamicin as a single agent. The secondary objective is to determine the safety profile of re-induction with gemtuzumab ozogamicin. When a complete response is achieved after 2 courses patients may proceed to stem-cell transplantation, and the number of patients that are eligible for a stem cell transplant is a secondary objective.

### Study objective

To assess whether children with relapsed/refractory AML, who do not achieve remission or relapse after treatment with the Relapsed AML 2001/01 standard reinduction protocol (fludarabine, cytarabine and GCSF with or without DaunoXome 1/2), can be salvaged by treatment with Mylotarg 1/2 (gemtuzumab ozogamicin) as a single agent. The principal endpoint is overall complete response.

### Study design

Patients will be evaluated after 2 courses of treatment.

## Intervention

Patients will be treated with 2 courses of gemtuzumab ozogamicin with a 14-day interval.

## Contacts

### Public

C.M. Zwaan  
Erasmus MC  
Dr Molewaterplein 60  
Rotterdam 3015 GJ  
The Netherlands

### Scientific

C.M. Zwaan  
Erasmus MC  
Dr Molewaterplein 60  
Rotterdam 3015 GJ  
The Netherlands

## Eligibility criteria

### Inclusion criteria

1. Children with primary refractory or relapsed AML, who do not respond to treatment according to the Relapsed AML 2001/01 re-induction protocol, defined as an M3 marrow after 1 course of chemotherapy or no CR after 2 courses of treatment according to this protocol (either FLAG or FLAG/DNX);
2. Children who relapse after having achieved CR by treatment according to the Relapsed AML 2001/01 trial;
3. Inclusion is NOT dependent on CD33 positivity of the AML cells (i.e. CD33 negative AMLi<sub>2</sub>s may also be included);
4. No contra-indication for chemotherapy;
5. Age <19 years;
6. A Karnofsky performance status >50% for patients over 15 years of age, or a Lansky performance status >50% for patients aged 15 years and younger;

7. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol;
8. Written informed consent, according to the guidelines of the local institution, is mandatory.

## Exclusion criteria

1. Isolated extramedullary relapse;
2. Active, symptomatic CNS leukemia in case of combined relapse;
3. Hepatic dysfunctioning: i.e. hepatic transaminases elevated more than 3 times above upper normal levels, or hyperbilirubinaemia ( $>20 \mu\text{mol/l}$ );
4. Impaired renal function (more than 2 times normal value for creatinine, adjusted for age).

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2002
Enrollment:	50
Type:	Actual

## Ethics review

Positive opinion

Date: 20-02-2009  
Application type: First submission

## 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	NL1600
NTR-old	NTR1680
Other	Relapsed AML I-BFM study/METC ErasmusMC : 2001/02/ 01/215
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A