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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21108

Source
NTR

Brief title
Relapsed AML 2001/02

Health condition

acute myeloid leukemia, AML, gemtzuzumab 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 prohression 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/m2 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/m2 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 DaunoXomeï¿½), can be salvaged by treatment with Mylotargï¿½ (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 AMLï¿½s 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 ï¿½mol/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