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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21108

Bron
NTR

Verkorte titel
Relapsed AML 2001/02

Aandoening

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

Ondersteuning

Primaire sponsor: VUmc, Amsterdam
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Overall response rate.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Patients will be evaluated after 2 courses of treatment.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-03-2002
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-02-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1600
NTR-old	NTR1680
Ander register	Relapsed AML I-BFM study/METC ErasmusMC : 2001/02/ 01/215
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A