Alemtuzumab as remission induction for adult patients with acute lymphoblastic leukemia in relapse; A randomized phase II study.

Gepubliceerd: 04-05-2006 Laatst bijgewerkt: 18-08-2022

The hypothesis to be tested is that arm A and/or arm B are feasible.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28605

Bron
NTR

Verkorte titel
HOVON 74 ALL

Aandoening

Acute lymphoblastic leukemia in relapse

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie Volwassenen Nederland (HOVON)
P/a HOVON Data Center
Erasmus MC - Daniel den Hoed
Postbus 5201
3008 AE Rotterdam
Tel: 010 4391568
Fax: 010 4391028
e-mail: hdc@erasmusmc.nl
Overige ondersteuning: HOVON receives unrestricted grants and/or financial support from Amgen, Johnson&Johnson-Orthobiotech, Roche and Novartis for the execution of investigator

sponsored trials. In addition HOVON is supported by the Dutch Cancer Society and for this specific trial also by Schering International.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Percentage of patients that reach a CR on induction cycle I in each arm;
2. Percentage of patients with severe toxicity on induction cycle I in each arm.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase: Randomized phase II
Study objective: Evaluation of feasibility of alemtuzumab in adult patients with relapsed ALL after a 1st or 2nd CR
Patient population: Patients, age 18 – 70 years inclusive, with relapsed ALL, non-mature B-cell
Study design: Prospective, multicenter, randomized
Duration of treatment: Expected duration of treatment will be approximately 11 weeks.

Doel van het onderzoek

The hypothesis to be tested is that arm A and/or arm B are feasible.

Onderzoeksproduct en/of interventie

Relapsed ALL patients under the age of 71 years will be registered and randomized to receive:
Arm A: prednisone and methotrexate in the pre-phase and thereafter two remission induction courses of alemtuzumab 30 mg.
Or
Arm B: prednisone and methotrexate in the pre-phase and thereafter two remission induction courses of alemtuzumab 60 mg.

Contactpersonen

Publiek

Leiden University Medical Center (LUMC), Department of Hematologie (C2-R),
P.O. Box 9600
R. Willemze
Leiden 2300 RC
The Netherlands
+31 (0)71 5262267

Wetenschappelijk

Leiden University Medical Center (LUMC), Department of Hematologie (C2-R),
P.O. Box 9600
R. Willemze
Leiden 2300 RC
The Netherlands
+31 (0)71 5262267

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18 - 70 years inclusive;
2. First or second relapse of precursor B-ALL or T-ALL (including Philadelphia chromosome or BCR-ABL positive ALL);
3. Duration of last complete remission at least 6 months;
4. WHO performance status 0, 1, or 2;
5. Negative pregnancy test at inclusion if applicable;
6. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Mature B-cell ALL, i.e. Burkitt leukemia/lymphoma;
2. Acute undifferentiated leukemia (AUL);
3. Treatment with alemtuzumab at any time prior to registration;
4. Intolerance of exogenous protein administration;
5. Central nervous system (CNS) leukemia (appendix A);
6. Severe cardiovascular disease (arrhythmias requiring chronic treatment, congestive heart failure or symptomatic ischemic heart disease);
7. Severe pulmonary dysfunction (CTCAE grade III-IV);

8. Severe neurological or psychiatric disease;
9. Significant hepatic dysfunction (serum bilirubin or transaminases >= 3 times normal level);
10. Significant renal dysfunction (serum creatinine >= 3 times normal level);
11. Patients with active, uncontrolled infections;
12. Patients with uncontrolled asthma or allergy, requiring oral steroid treatment at the time of registration;
13. Patients known to be HIV-positive;
14. Patient is a lactating woman;
15. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-05-2006
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-05-2006
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	NL614
NTR-old	NTR673
Ander register	: HO74
ISRCTN	ISRCTN86445183

Resultaten

Samenvatting resultaten
N/A