Early intensification by (un)related allogeneic or autologous stem cell transplantation in adult acute lymphoblastic leukemia. A phase II study.

Gepubliceerd: 06-09-2005 Laatst bijgewerkt: 13-12-2022

Patients who are in 1st CR after autologous transplantation, may be randomized between no further treatment (arm A) and maintenance chemotherapy (arm B). The hypothesis to be tested is that maintenance therapy will prolong disease free survival,...

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

Samenvatting

ID

NL-OMON20150

Bron
NTR

Verkorte titel
HOVON 37 ALL

Aandoening

Acute Lymphoblastic Leukemia (ALL).

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor 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: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
Koningin Wilhelmina Fonds (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Response after each course of chemotherapy and date of CR.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase:

phase 2.

Study objectives:

1. To study prospectively the value of early intensification by allogeneic or autologous stem cell transplantation in ALL;

2. To study prospectively stem cell transplantation with a matched unrelated donor in high-risk ALL when no sibling donor is available;

3. To study the value of donor lymphocyte infusion (DLI) in high-risk ALL with a molecular or cytogenetic relapse after allogeneic stem cell transplantation or in high-risk ALL with persistent residual disease (molecular; cytogenetic);

4. To study the value of maintenance chemotherapy in ALL patients after autologous transplantation;

5. To study leukemic cell reduction by means of (semi-quantitative) molecular techniques during induction chemotherapy, after consolidation with stem cell transplantation, and during maintenance chemotherapy in patients receiving an autologous stem cell transplantation.

Patient population:

Patients with previously untreated, B-precursor ALL, T-ALL or AUL, age 16-59 years inclusive.

Study design:

Prospective, multicenter, randomized.

Doel van het onderzoek

Patients who are in 1st CR after autologous transplantation, may be randomized between no further treatment (arm A) and maintenance chemotherapy (arm B). The hypothesis to be tested is that maintenance therapy will prolong disease free survival, calculated from the date of randomization.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

All patients will receive early intensification:

- cycle 1: prednisone, vincristine, daunorubicin, aspariganse, MTX i.t.

- cycle 2: Cytarabine, Mitoxantrone, MTX i.t.

- cycle 3: Methotrexate, asparaginase, 6-MP, MTX i.t.

After intensification patients will receive either an allogeneic sibling stem cell transplantation, a matched unrelated donor stem cell transplantation or an autologous stem cell transplantation.

Patients who received an autologous stem cell transplantation will be randomized between:

- Arm A: no further treatment.

- Arm B: maintenance treatment with 6-MP and MTX.

Contactpersonen

Publiek

University Medical Center Utrecht (UMCU),
Department of Hematology, (G03.647),
P.O. Box 85500
A.W. Dekker
Utrecht 3508 GA
The Netherlands
+31 (0)30 2507655

Wetenschappelijk

University Medical Center Utrecht (UMCU),
Department of Hematology, (G03.647),
P.O. Box 85500
A.W. Dekker
Utrecht 3508 GA
The Netherlands
+31 (0)30 2507655

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 16 and 59 (inclusive) years;

2. Previously untreated with chemotherapy;

3. ALL according to the FAB criteria and immunological marker analysis (B-precursor ALL, T-ALL and AUL);

4. WHO performance status grade 0, 1, 2 or 3;

5. Patient informed consent.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. B-ALL (= mature B-ALL);

2. Severe cardiac, pulmonary, hepatic, renal, neurologic, psychiatric or metabolic disease;

3. Second malignant disease, except cervix carcinoma stage I and non-melanoma skin cancer;

4. Persisting renal insufficiency, creatinine more than 200 mmol/l;

5. Active uncontrolled infections;

6. HIV positivity on serological tests.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-1999
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2005

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	NL191
NTR-old	NTR228
Ander register	: HO37
ISRCTN	ISRCTN77441569

Resultaten

Samenvatting resultaten
N/A