Clofarabine added to prephase and consolidation therapy in acute lymphoblastic leukemia in adults.

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The hypothesis to be tested in the phase II part is that arm B is feasible. The hypothesis to be tested in the phase III part is that the outcome in arm B is better than in arm A.

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

Samenvatting

ID

NL-OMON28093

Bron
NTR

Verkorte titel
HOVON 100 ALL

Aandoening

Acute Lymphoblastic Leukemia (ALL)

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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Overige ondersteuning: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON), Koningin Wilhelmina Fonds (KWF), Genzyme, MEDAC.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Phase II part: To determine the feasibility of adding i.v. clofarabine to standard prephase therapy (followed by induction chemotherapy);
2. Phase III part: To improve EFS in adult ALL patients by the addition of i.v. clofarabine to prephase and consolidation therapy .

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase: Phase II/III.

Study objective:

Phase II: To determine the feasibility of i.v. clofarabine given prior to standard induction chemotherapy as part of pre-phase.

Phase III: To improve event free survival by adding i.v. clofarabine to prephase and consolidation therapy
Patient population: Patients with previously untreated ALL, age 18-70 years.

Study design:

Phase II: Comparative, randomized feasibility study (dose-finding) of clofarabine chemotherapy at three possible dose levels 15, 20, or 30 mg/m2.

Phase III: Multicenter study at the selected feasible dose level of clofarabine in a prospective randomized approach between clofarabine combined with pre-phase therapy and in an extra consolidation cycle versus the same chemotherapy without addition of clofarabine.

Duration of treatment:
Expected duration of 32 months, maintenance therapy of 24 months inclusive.
All patients will be followed until 10 years after randomization.

Doel van het onderzoek

The hypothesis to be tested in the phase II part is that arm B is feasible.

The hypothesis to be tested in the phase III part is that the outcome in arm B is better than in arm A.

Onderzoeksopzet

1. At entry;

2. Pre-phase;

3. Induction;

4. Consolidation;

5. Interphase;

6. Intensification;

7. Allo-SCT;

8. Maintenance;

9. Follow-up (every 6 months.

Onderzoeksproduct en/of interventie

In the experimental arm B intravenously administered clofarabine will be added to standard prephase chemotherapy and used in an extra consolidation cycle. Arm A is the standard arm. The study starts at a dose level of 20 mg/m2, and if possible escalating to 30 mg/m2. If 20 mg/m2 is not feasible we will study 15 mg/m2.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients aged 18 to 70 years inclusive;

2. Primary previously untreated B or T-lineage ALL (excluding -ALL with mature B-cell phenotype, but including Philadelphia positive or BCR-ABL positive ALL);

3. Adequate renal and hepatic function tests as indicated by the following laboratory values:

A. Serum creatinine ¡Ü1.0 mg/dl (¡Ü 88.7 micromol/L); if serum creatinine >1.0 mg/dl (>88.7 micromol/L), then the glomerular filtration rate (GFR) must be >60 ml/min/1.73 m2 as calculated by the Modification of Diet in Renal Disease equation where the predicted GFR (ml/min/1.73 m2) = 186 x (Serum Creatinine in mg/dl)-1.154 x (age in years)-0.023 x (0.742 if patient is female) x (1.212 if patient is black)NOTE: if serum creatinine is measured in micromol/L, recalculate it in mg/dl according to the equation: 1 mg/dl = 88.7 micromol/L) and used above mentioned formula;

B. Serum bilirubin ¡Ü 1.5 ¡Á upper limit of normal (ULN);

C. Aspartate transaminase (AST)/alanine transaminase (ALT) ¡Ü 2.5 ¡Á ULN;

D. Alkaline phosphatase ¡Ü 2.5 ¡Á ULN.

4. WHO performance status 0 ¨C 2;

5. Negative pregnancy test at inclusion, if applicable;

6. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Mature surface Ig positive B-cell leukemia/lymphoma;

2. Acute undifferentiated leukemia;

3. Severe cardiovascular disease (arrhythmias requiring chronic treatment, congestive heart failure or symptomatic ischemic heart disease);

4. Severe pulmonary dysfunction (CTCAE grade III-IV, see appendix D);

5. Severe neurological or psychiatric disease;

6. History of active malignancy during the past 5 years with the exception of basal carcinoma of the skin or stage 0 cervical carcinoma;

7. Active, uncontrolled infection;

8. Patient known to be HIV-positive;

9. Patient is a lactating woman;

10. Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule;

11. Unwilling or not capable to use effective means of birth control.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-01-2009
Aantal proefpersonen:	340
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-09-2009
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	NL1890
NTR-old	NTR2004
Ander register	EudraCT 2008-005798-36 : Ho100
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A