A randomized phase III study in previously untreated patients with biological high-risk CLL: Fludarabine + cyclophosphamide (FC) versus FC + low-dose alemtuzumab.

Gepubliceerd: 30-11-2005 Laatst bijgewerkt: 18-08-2022

The hypothesis to be tested 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-OMON25345

Bron
NTR

Verkorte titel
HOVON 68 CLL

Aandoening

Chronic Lymphocytic Leukemia

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Progression free survival (i.e. time from registration to disease progression, relapse or death due to CLL whichever occurs first).

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase: Phase III

Study objectives: Determination of the efficacy and safety of oral fludarabine and cyclophosphamide plus concomitant s.c. alemtuzumab compared to fludarabine and cyclophosphamide alone in terms of progression free survival, event free survival, clinical, flow cytometric and molecular response rates, overall survival and disease free survival.

Patient population: Patients with biological high-risk CLL in symptomatic stage A or B or stage C, irrespective of duration of disease, age 18-75 years inclusive.

Study design: Prospective, multicenter, randomized

Duration of treatment: Expected duration of treatment is 24 weeks.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

All eligible patients will be randomized on entry between:

1. Arm A: 6 cycles of oral FC;

2. Arm B: 6 cycles of oral FC combined with s.c. alemtuzumab.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Biological high-risk CLL;

2. Patients with symptomatic stage A, symptomatic stage B or stage C;

3. Age 18-75 years inclusive;

4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. WHO performance status >= 3, unless related to CLL;

2. Intolerance of exogenous protein administration;

3. Severe cardiac dysfunction (NYHA classification III-IV);

4. Significant renal dysfunction (serum creatinine >= 150 micromol/l or creatinine clearance < 30 ml/min);

5. Significant hepatic dysfunction (total bilirubin or transaminases > 2 times ULN), unless related to CLL;

6. Suspected or documented CNS involvement by CLL;

7. Known HIV positivity;

8. Active, uncontrolled infections;

9. Uncontrolled asthma or allergy requiring systemic steroid treatment;

10. Previously treated with chemotherapy, radiotherapy or immunotherapy for CLL;

11. History of active cancer during the past 5 years, except non-melanoma skin cancer or stage 0 cervical carcinoma;

12. Clinically significant auto-immune hemolytic anemia (AIHA);

13. Female patients who are pregnant or nursing;

14. Male and female patients of reproductive potential who are not practicing effective means of contraception, these include oral contraceptives, intrauterine device, depot injection of gestagen, subdermal implantation, hormonal vaginal ring and transdermal depot plaster.
These methods must be applied for the entire protocol treatment period, and for patients treated with alemtuzumab until at least 6 months after the end of alemtuzumab administration.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-12-2005
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-11-2005
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	NL487
NTR-old	NTR529

Register	ID
Ander register	: HO68
ISRCTN	ISRCTN25180151

Resultaten

Samenvatting resultaten
N/A