Imatinib in combination with Cytarabine as compared to Imatinib alone in patients with first chronic phase Chronic Myeloid Leukemia. A prospective randomized phase III study.

Gepubliceerd: 04-05-2006 Laatst bijgewerkt: 13-12-2022

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

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

Samenvatting

ID

NL-OMON21778

Bron
Nationaal Trial Register

Verkorte titel
HOVON 78 CML

Aandoening

First chronic phase Chronic Myeloid Leukemia

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

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Rate of major molecular response at 12 months from randomization.

Toelichting onderzoek

Achtergrond van het onderzoek

- Study phase: Phase III
- Study objectives: To determine the efficacy of the combination of imatinib with cytarabine as compared to imatinib alone in terms of the rate of molecular response at 12 months from randomization.
- Patient population: Patients with Chronic Myeloid Leukemia, Philadelphia-positive (cytogenetics) or bcr-abl positive (PCR), in first chronic phase <= 2 months from diagnosis, age 18-65 years inclusive
- Study design: Prospective, multicenter, randomized
- Duration of treatment: Until progression

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

Patients meeting all eligibility criteria will be randomized between:

Arm A: imatinib given orally at a total dose of 800 mg daily until progression;
OR
Arm B: imatinib given orally at a total dose of 800 mg daily, combined with 2 successive cycles of i.v. cytarabine 200 mg/m^2, at day 1-7, in cycles I and II, followed by imatinib monotherapy (800 mg daily) until progression.

Contactpersonen

Publiek

Erasmus Medical Center, Daniel den Hoed Cancer Center, Department of Hematology,
P.O. Box 5201
J.J. Cornelissen
Rotterdam 3008 AE
The Netherlands
+31 (0)10 4391598 or +31 (0)10 4391367

Wetenschappelijk

Erasmus Medical Center, Daniel den Hoed Cancer Center, Department of Hematology,
P.O. Box 5201
J.J. Cornelissen
Rotterdam 3008 AE
The Netherlands
+31 (0)10 4391598 or +31 (0)10 4391367

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Newly diagnosed patients with CML in first chronic phase <= 2 months;
2. Presence of Philadelphia chromosome or bcr-abl rearrangement;
3. Age 18-65 years inclusive;
4. WHO performance status <= 2;
5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. CML in accelerated phase or blastic crisis as defined by the WHO criteria;
2. Hepatic dysfunction (serum bilirubin >= 2 x N, and/or ALAT >= 4 x N, and/or ASAT >= 4 x N);
3. Renal dysfunction (creatinine >= 200 micromol/l or 2.3 mg/dl);
4. Severe cardiac dysfunction (NYHA classification II-IV);
5. Severe pulmonary or neurologic disease;
6. Pregnant or lactating females;

7. Patients with a history of active malignancy during the past 5 years with the exception of basal carcinoma of the skin or stage 0 cervical carcinoma;
8. Patients known to be HIV-positive;
9. Patients with active, uncontrolled infections;
10. Previous treatment other than hydroxyurea <= 2 months or imatinib <= 1 month;
11. Male and female patients of reproductive potential who are not practicing effective means of contraception.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-05-2006
Aantal proefpersonen:	330
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	NL615
NTR-old	NTR674
Ander register	: HO78
ISRCTN	ISRCTN51564734

Resultaten

Samenvatting resultaten
N/A