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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21778

Source
Nationaal Trial Register

Brief title
HOVON 78 CML

Health condition

First chronic phase Chronic Myeloid Leukemia

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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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.

Intervention

Outcome measures

Primary outcome

Rate of major molecular response at 12 months from randomization.

Secondary outcome

1. Rate and duration of major and complete molecular response;
2. Rate and duration of major and complete cytogenetic response;
3. Rate and duration of complete hematological response;
4. Progression-free survival (i.e. time from registration to progression or death from any cause, whichever occurs first);
5. Overall survival measured from the time of registration. Patients still alive or lost to follow up are censored at the date they were last known to be alive;
6. Toxicity;
7. Actual dose-intensity of imatinib delivered;
8. Incidence of mutations of abl-kinase domain.

Study description

Background summary

- 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

Study objective

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2006
Enrollment:	330
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-05-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL615
NTR-old	NTR674
Other	: HO78
ISRCTN	ISRCTN51564734

Study results

Summary results
N/A