

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.

Submission date 07/06/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 07/06/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/01/2021	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HO78, NL615, NTR674

Study information

Scientific Title

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.

Acronym

HOVON 78 CML

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

A prospective randomized, parallel group, phase III study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic myeloid leukemia

Interventions

Patients meeting all eligibility criteria will be randomized between:

Arm A: imatinib given orally at a total dose of 800 mg daily until progression

Arm B: imatinib given orally at a total dose of 800 mg daily, combined with 2 successive cycles of intravenous (i.v.) cytarabine 200 mg/m², at day 1-7, in cycles I and II, followed by imatinib monotherapy (800 mg daily) until progression

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Imatinib, cytarabine

Primary outcome(s)

Rate of major molecular response at 12 months from randomization

Key secondary outcome(s)

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

Completion date

08/05/2011

Eligibility

Key inclusion criteria

1. Newly diagnosed patients with chronic myeloid leukemia (CML) in first chronic phase $\leq$ 2 months
2. Presence of Philadelphia chromosome or bcr-abl rearrangement
3. Age 18-65 years inclusive
4. World Health Organization (WHO) performance status $\leq$ 2
5. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Total final enrolment

109

Key exclusion criteria

1. CML in accelerated phase or blastic crisis as defined by the WHO criteria
2. Hepatic dysfunction (serum bilirubin $\geq$ 2 x upper limit of normal [ULN], and/or alanine aminotransferase [ALAT] $\geq$ 4 x ULN, and/or aspartate aminotransferase [ASAT] $\geq$ 4 x ULN)
3. Renal dysfunction (creatinine $\geq$ 200 μ mol/l or 2.3 mg/dl)

4. Severe cardiac dysfunction (New York Heart Association [NYHA] classification II-IV)
5. Severe pulmonary or neurological 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 human immunodeficiency virus (HIV)-positive
9. Patients with active, uncontrolled infections
10. Previous treatment other than hydroxyurea for $\leq$ 2 months or imatinib for $\leq$ 1 month
11. Male and female patients of reproductive potential who are not practicing effective means of contraception

Date of first enrolment

08/05/2006

Date of final enrolment

08/05/2011

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

3008 AE

Sponsor information

Organisation

Dutch Haemato-oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON)

ROR

<https://ror.org/056kpx27>

Funder(s)

Funder type

Industry

Funder Name

Roche Nederland BV

Funder Name

Dutch Cancer Society

Funder Name

Amgen

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Johnson and Johnson-Orthobiotech

Funder Name

Novartis Pharma B.V.

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2013	08/01/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes

