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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

Registration date
07/06/2006

Overall study status
Completed

Last Edited
08/01/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hovon.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
A prospective randomized, parallel group, phase III study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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/m^2, 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 measure
Rate of major molecular response at 12 months from randomization

Secondary outcome measures
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

Overall study start date
08/05/2006

Completion date
08/05/2011

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
330

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 >/= 2 x upper limit of normal [ULN], and/or alanine aminotransferase [ALAT] >/= 4 x ULN, and/or aspartate aminotransferase [ASAT >/= 4 x ULN)
3. Renal dysfunction (creatinine >/= 200 µmol/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 </= 2 months or imatinib for </= 1 month
11. Male and female patients of reproductive potential who are not practicing effective means of contraceptio

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)

Sponsor details
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Sponsor type
Research organisation

ROR
https://ror.org/056kpdx27

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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