

High-dose cytarabin versus low-dose cytarabin plus interferon-alpha-2a both followed by maintenance with interferon-alpha-2a in chronic myeloid leukemia

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 15/05/2009	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NTR290; Ho38

Study information

Scientific Title

Acronym

HOVON 38 CML

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre randomised active controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic myeloid leukemia (CML)

Interventions

Induction therapy with hydroxyurea (3 - 4 weeks). Patients less than or equal to 55 years with a HLA identical sibling proceed to allo-BMT. All other patients are randomised between:

Arm A: Cycle I: cytarabin/idarubicin, Cycle II: high-dose cytarabin; maintenance with interferon-alpha-2a

Arm B: Low-dose cytarabin and interferon-alpha-2a; maintenance with interferon-alpha-2a

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Cytarabin, idarubicin, interferon-alpha-2a, hydroxyurea

Primary outcome(s)

Event-free survival

Key secondary outcome(s)

1. Haematological and cytogenetical remission
2. Overall survival
3. Remission duration

Completion date

15/06/2001

Eligibility

Key inclusion criteria

1. Newly diagnosed patients with chronic myeloid leukemia (CML) in first chronic phase less than or equal to 6 months
2. Presence of Philadelphia chromosome or BCR/ABL rearrangement
3. Age 16 - 65 years inclusive
4. World Health Organisation (WHO) performance scale less than or equal to 2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. CML in blastic phase
2. CML in accelerated phase
3. Hepatic dysfunction (bilirubin greater than or equal to 2 x normal, and/or alanine aminotransferase [ALAT] greater than 4 x normal)
4. Renal dysfunction (creatinine greater 200 $\mu\text{mol/l}$ or 23 mg/dl)
5. Patients with severe cardiac, pulmonary or neurologic disease
6. Pregnant or lactating females
7. Human immunodeficiency virus (HIV) infection
8. Other malignancies, except stage I cervix carcinoma and basocellular carcinoma

Date of first enrolment

23/01/1998

Date of final enrolment

15/06/2001

Locations

Countries of recruitment

Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3008 AE

Sponsor information

Organisation

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

ROR

<https://ror.org/056kpdx27>

Funder(s)

Funder type
Industry

Funder Name

Commission for Medical Applied Research (Commissie voor Klinisch Toegepast Onderzoek [CKTO]) (Netherlands)

Funder Name

Johnson & Johnson (Netherlands)

Alternative Name(s)

Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson&Johnson, Johnson & Johnson Private Limited, , , J&J, JNJ

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Amgen (Netherlands)

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

Roche Nederland BV (Netherlands)

Funder Name

Novartis Pharma BV (Netherlands)

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes