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

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.hovon.nl

Contact information

Type(s)

Scientific

Contact name

Dr J.J. Cornelissen

Contact details

Erasmus Medical Centre
Daniel den Hoed Cancer Centre
Department of Haematology
P.O. Box 5201
Rotterdam
Netherlands
3008 AE
+31 (0)10 439 1598
j.cornelissen@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Multicentre randomised active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 interferonalpha-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 measure

Event-free survival

Secondary outcome measures

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

Overall study start date

23/01/1998

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

Age group

Adult

Sex

All

Target number of participants

102

Key exclusion criteria

- 1. CML in blastic phase
- 2. CML in accelerated phase
- 3. Hepatic dysfunction (bilirubin greater than or equal to 2×10^{-2} x normal, and/or alanine aminotransferase [ALAT] greater than 4×10^{-2} x normal)

- 4. Renal dysfunction (creatinine greater 200 mumol/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)

Sponsor details

Vrije University Medical Centre (VUMC) PO Box 7057 Amsterdam Netherlands 1007 MB +31 (0)20 444 2693 hdc@hovon.nl

Sponsor type

Research organisation

Website

http://www.hovon.nl/

ROR

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 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

Publication and dissemination planNot 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