ISRCTN84226319 https://doi.org/10.1186/ISRCTN84226319

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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
15/05/2009

Condition category
Cancer

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

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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 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 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
Both

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 x normal, and/or alanine aminotransferase [ALAT] greater than 4 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
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Netherlands
1007 MB
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hdc@hovon.nl

Sponsor type
Research organisation

Website
http://www.hovon.nl/

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

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