

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

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/05/2009	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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](mailto: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 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  $\mu\text{mol/l}$  or 23  $\text{mg/dl}$ )
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 & 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