

Risk adapted treatment of Acute Myelocytic Leukaemia (AML)

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 23/10/2007	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

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Additional identifiers

Protocol serial number
HO29

Study information

Scientific Title

Acronym

HOVON 29 AML/SAKK 30/95

Study objectives

The hypotheses to be tested are that:

1. The outcome in arm B is better than in arm A
2. Following Peripheral Blood Stem Cell Transplant (PBSCT) is better than following Cycle III chemotherapy

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute Myeloid Leukaemia (AML)

Interventions

Patients (except AML-M3 or t[15;17]) will be randomised on entry between:

Arm A:

Cycle I: idarubicin + cytarabin

Cycle II: amsacrin + cytarabin

Arm B:

Cycle I: idarubicin + cytarabin + G-CSF

Cycle II: amsacrin + cytarabin + G-CSF

Patients with AML-M3 or t(15;17) will receive arm A treatment. Patients in Complete Remission (CR) with good risk will proceed to cycle III: Mitoxantrone + VP-16. Patients in CR with poor risk and a HLA matched donor will proceed to Allo BMT. Patients in CR with poor risk without a HLA matched donor will be randomised between cycle III chemotherapy and Busulfan /Cyclophosphamide marrow ablative treatment and PBSCT.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

CR rate.

Key secondary outcome(s))

1. Disease-free survival
2. Overall survival

Completion date

06/06/2001

Eligibility

Key inclusion criteria

First randomisation:

1. Patients with newly diagnosed de novo Acute Myelocytic Leukaemia (AML) (including all cytological subtypes M0-M7)
2. Age 15 - 60 years inclusive
3. Patients have given informed consent
4. Leucocytosis (White Blood Cells [WBC] greater than $30 \times 10^9/l$) is not an exclusion criterion, but it will require postponement of Granulocyte-Colony Stimulating Factor (G-CSF) administration until WBC have declined to $20 \times 10^9/l$ on chemotherapy

Patients after completion of CYCLE II and peripheral blood stem cell collection are eligible for second randomisation if:

1. Complete remission continues (marrow cytology and blood evaluation)
2. Poor risk status according to criteria of Appendix III
3. Not eligible for genotypically Human Leukocyte Antigen (HLA) matched allogeneic Bone Marrow Transplant (BMT)
4. Absence of congestive heart failure or pulmonary disease
5. Serum bilirubin as parameter of liver function abnormalities not elevated above 3 x normal value
6. Number of blood cells collected ('transplant'; PBSCT) being at least 2×10^8 nucleated cells/kg or 10×10^4 Colony-Forming Units Granulocyte-Macrophage (CFU-GM) per kg or 2×10^6 CD34-positive cells per kg. In case of no or insufficient PBSCT, an adequate autologous marrow graft must have been collected
7. Performance status of World Health Organization (WHO) grade 0, 1 or 2 at time of randomisation
8. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

First randomisation:

1. Patients with a concurrent active malignancy, except stage I cervix carcinoma and basocellular carcinoma
2. Patients previously treated with chemotherapy
3. Leukaemia following from a documented myelodysplasia with a duration of more than 6 months
4. Blastic crisis of chronic myeloid leukaemia or leukaemia developing from myeloproliferative diseases (e.g. polycythemia vera, myelofibrosis)
5. Renal or liver function abnormalities i.e. creatinine and bilirubin of more than 3 x normal value, except if directly attributable to the leukaemia (high serum lysosymes, hyperuricemia, leukaemic cell infiltration)
6. Human Immunodeficiency Virus (HIV) positive serology
7. Patients with severe cardiac, pulmonary or neurologic disease
8. Pregnancy

Date of first enrolment

30/03/1995

Date of final enrolment

06/06/2001

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/056kpx27>

Funder(s)

Funder type

Industry

Funder Name

Amgen (The 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

Novartis (The Netherlands)

Alternative Name(s)

Novartis AG, Novartis International AG

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Funder Name

Pharma B.V. (The Netherlands)

Funder Name

Roche Nederland B.V. (The Netherlands)

Funder Name

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

Funder Name

Johnson & Johnson (The 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

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration