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Risk adapted treatment of Acute Myelocytic Leukaemia (AML)

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
23/10/2007	Cancer	[ ] 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 x 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 x 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 x 10^8 nucleated cells /kg or 10 x 10^4 Colony-Forming Units Granulocyte-Macrophage (CFU-GM) per kg or 2 x 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/056kpdx27

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