Risk adapted treatment of acute myelocytic leukemia (AML).

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The hypotheses to be tested are that the outcome: 1. In arm B is better than in arm A; 2. Following PBSCT is better than following Cycle III chemotherapy.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27294

Bron
NTR

Verkorte titel
HOVON 29 AML/SAKK 30/95

Aandoening

Acute myelocytic leukemia.

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
Erasmus MC - Daniel den Hoed
Postbus 5201
3008 AE Rotterdam
Tel: 010 4391568
Fax: 010 4391028
e-mail: hdc@erasmusmc.nl
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

CR rate.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase: phase III;

Study objective:

Evaluation of the effect of GCSF during induction treatment, evaluation of endpoints after Cycle III chemotherapy, PBSCT and Allo BMT. Evaluation of validity of previously established risk parameters. Assessment of the practical applicability of PBSCT in patients with AML. Assessment of the outcome after Allo BMT in comparison to PBSCT and Cycle III chemotherapy.

Patient population:

patients with newly diagnosed de novo AML, age 15-60 yrs inclusive.

Study design:

prospective, multicenter, randomized.

Duration of treatment:

expected duration of induction treatment is about 2 months.

Doel van het onderzoek

The hypotheses to be tested are that the outcome:

1. In arm B is better than in arm A;

2. Following PBSCT is better than following Cycle III chemotherapy.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients (except AML-M3 or t(15;17)) will be randomized 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 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 randomized between :

Cycle III chemotherapy and

Busulfan/Cyclophosphamide marrow ablative treatment and PBSCT.

Contactpersonen

Publiek

Erasmus Medical Center, Daniel den Hoed Cancer Center, Department of Hematology,
P.O. Box 5201
B. Löwenberg
Rotterdam 3008 AE
The Netherlands
+31 (0)10 4391598

Wetenschappelijk

Erasmus Medical Center, Daniel den Hoed Cancer Center, Department of Hematology,
P.O. Box 5201
B. Löwenberg
Rotterdam 3008 AE
The Netherlands
+31 (0)10 4391598

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

First randomization:

1. Patients with newly diagnosed de novo AML (including all cytological subtypes M0-M7);

2. Age 15-60 yrs inclusive;

3. Patients have given informed consent;

4. Leucocytosis (WBC >30 x 109/l) is not an exclusion criterium, but it will require postponement of 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 randomization if:

5. Complete remission continues (marrow cytology and blood evaluation);

6. Poor risk status according to criteria of Appendix III;

7. Not eligible for genotypically HLA matched allogeneic BMT;

8. Absence of congestive heart failure or pulmonary disease;

9. Serum bilirubin as parameter of liver function abnormalities not elevated above 3 x normal value;

10. Number of blood cells collected ("transplant"; PBSCT) being at least 2 x 108 nucleated cells/kg or 10 x 10^4 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;

11. Performance status of WHO grade 0, 1 or 2 at time of randomization;

12. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

First randomization:

1. Patients with a concurrent active malignancy, except stage I cervix carcinoma and basocellular carcinoma;

2. Patients previously treated with chemotherapy;

3. Leukemia following from a documented myelodysplasia with a duration of more than 6 months;

4. Blastic crisis of chronic myeloid leukemia or leukemia 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 leukemia (high serum lysosymes, hyperuricemia, leukemic cell infiltration);

6. HIV positive serology;

7. Patients with severe cardiac, pulmonary or neurologic disease;

8. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	30-03-1995
Aantal proefpersonen:	1105
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL253
NTR-old	NTR291
Ander register	: HO29
ISRCTN	ISRCTN76815071

Resultaten

Samenvatting resultaten

1. G.E. de Greef, W.L. van Putten, M. Boogaerts, P.C. Huijgens, L.F. Verdonck, E. Vellenga, M. Theobald, E. Jacky and B. Löwenberg; The Dutch-Belgian Hemato-Oncology Co-operative Group HOVON; The Swiss Group for Clinical Cancer Research SAKK. Criteria for defining a complete remission in acute myeloid leukaemia revisited. An analysis of patients treated in HOVON-SAKK co-operative group studies. British Journal of Haematology, 128(2), 184-191. 2005 (also data of HOVON 4 and 4A);
2. D.A. Breems, W.L. van Putten, P.C. Huijgens, G.J. Ossenkoppele, G.E. Verhoef, L.F. Verdonck, E. Vellenga, G.E. de Greef, E. Jacky, J. van der Lelie, M.A. Boogaerts and B. Löwenberg. Prognostic Index for Adult Patients With Acute Myeloid Leukemia in First Relapse. Journal of Clinical Oncology, 2005 Jan 4; [Epub ahead of print] (also data of HOVON 4 and 4A);
3. B. Löwenberg, W. van Putten, M. Theobald, J. Gmür, L. Verdonck, P. Sonneveld, M. Fey, H. Schouten, G. de Greef, A. Ferrant, T. Kovacsovics, A. Gratwohl, S. Daenen, P. Huijgens, M. Boogaerts; Dutch-Belgian Hemato-Oncology Cooperative Group; Swiss Group for Clinical Cancer Research. Effect of priming with granulocyte colony-stimulating factor on the outcome of chemotherapy for acute myeloid leukemia. The New England Journal of Medicine, 349(8), 743-752. 2003;

4. E. Vellenga, W.L.J. van Putten, M.A. Boogaerts, S.M.G.J. Daenen, G.E.G. Verhoef, A. Hagenbeek, A.R. Jonkhoff, P.C. Huijgens, L.F. Verdonck, J. van der Lelie, H.C. Schouten, J. Gmür, P. Wijermans, A. Gratwoh, U. Hess, M.F. Fey and B. Löwenberg. Peripheral blood stem cell transplantation as an alternative to autologous marrow transplantation in the treatment of acute myeloid leukemia. Bone Marrow Transplantation, 23, 1279-1282. 1999.