Prevention of severe GVHD after allogeneic hematopoietic stem cell transplantation, applied as consolidation immunotherapy in patients with hematological malignancies. A prospective randomized phase III trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28315

Source
NTR

Brief title
HOVON 96 GVHD

Health condition

Randomization 1:
Patients planned to undergo an allogeneic SCT for
malignant hematological disorders and with a related or unrelated 8/8 HLA matched donor.

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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Source(s) of monetary or material Support: HOVON receives unrestricted financial support from Novartis and Fresenius for the execution of this investigator initiated trial. In addition HOVON is supported by the Dutch Cancer Society.

Intervention

Outcome measures

Primary outcome

Randomization 1:

Proportion of patients with non-severe GVHD (acute GVHD grade I, grade II without gut infiltration, or chronic GVHD not requiring systemic treatment) within D180 after randomization.

Secondary outcome

Randomization 1:

1. Time to acute GVHD grade I, II, III, IV;

2. Cumulative incidence of progression;

3. Progression-free survival (defined as time from randomization 1 until progression or death, whichever occurs first);

4. Cumulative incidence of non-relapse mortality;

5. Overall survival (cause of death should be defined according to Appendix F);

6. Time to chronic GVHD limited and extensive;

7. Adverse events;

8. ƒ{ƒnQuality of life as defined by the EORTC QLQ-C30 and the FACT-BMT definitions.

Study description

Background summary

Study phase:

Phase III.

Objectives R1:

1. To reduce the proportion of patients without GVHD within 180 days post-allo-SCT;

2. To reduce the progression rate;

3. To improve the progression free survival;

4. To asses the impact on the quality of life
using a time restricted immunosuppressive regimen as compared to a prolonged, standard immunosuppressive regimen.

Additional objectives:

1. To develop a predictive score, by means of clinical and laboratory parameters (using genomic and proteomic approaches) that allows for accurate identification of patients at high risk of severe GVHD as well as for identification of patients, who will not develop GVHD.

Patient population:

All patients planned to undergo an allogeneic SCT for malignant hematological disorders and with a related or unrelated 8/8 HLA matched donor are eligible for randomization 1. No ATG will be given pre-transplantation as part of the conditioning regimen.

Study design:

Prospective, multicenter, open-label randomized.

Duration of treatment:

The expected duration of full dose immunosuppressive treatment after randomization 1 will be 84 to 180 days.

Study objective

Randomization 1:

The hypothesis to be tested is that the outcome in arm B is better than in arm A.

Study design

Clinical and laboratory evaluations:

Randomization 1:

1. At entry (before start of conditioning);

2. At day 0, 14 and 28;

3. Thereafter monthly during first year after allo-SCT;

4. Every 6 months from 1-5 yr after allo-SCT.

Quality of life:

1. At entry, i.e. at admission prior to the initiation of the conditioning regimen;

2. At 180 days after allo-SCT;

3. At 1 year after allo-SCT;

4. At 2 years after allo-SCT;

5. At 5 years after allo-SCT.

The quality of life measurements will be stopped at progression.

Intervention

Patients planned to undergo an allogeneic SCT for malignant hematological disorders and with a related or unrelated 8/8 HLA matched donor will be randomized to either standard immunosuppression (arm 1) or time restricted immunosuppression (arm 2). No ATG will be given pretransplantation as part of the conditioning regimen.

Contacts

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Eligibility criteria

Inclusion criteria

Randomization 1:

1. Age 18-65 inclusive;

2. AML, MDS, ALL, MM, CML, CLL, NHL, HL, or a myeloproliferative disease (MPD);

3. Planned allogeneic stem cell transplantation;

4. Related or unrelated donor with a 8/8 HLA match (HLA A, B, C, DRB1);

5. WHO performance status 0-2;

6. Written Informed Consent;

7. Negative pregnancy test (if applicable);

8. Patients who are willing and capable to use adequate contraception during Myfortic treatment (all pre-menopausal women).

Exclusion criteria

Randomization 1:

1. Renal dysfunction (serum creatinine > 150 µmol/L or clearance < 50 ml/min);

2. Patients with active, uncontrolled infection;

3. Cord Blood transplantation;

4. Patients receiving ATG pre-transplantation as part of the conditioning regimen;

5. Patients with progressive disease in case of MM, CLL, NHL, HL;

6. Patients with > 5% marrow blasts in case of AML, ALL, CML;

7. Patients with EMD in case of AML, ALL, CML.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-03-2010
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-03-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2128
NTR-old	NTR2252
Other	EudraCT : 2008-003540-11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A