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.

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Randomization 1: The hypothesis to be tested is that the outcome in arm B is better than in arm A.

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

Samenvatting

ID

NL-OMON28315

Bron
NTR

Verkorte titel
HOVON 96 GVHD

Aandoening

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

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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Overige ondersteuning: 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.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Randomization 1:

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-03-2010
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-03-2010
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	NL2128
NTR-old	NTR2252
Ander register	EudraCT : 2008-003540-11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A