Tracing stem cells after transplantation

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Hematopoiesis after transplantation is supported by a limited number of HSCs, and the proliferative stress posed upon these cells compromises their long-term genomic and functional integrity,

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23273

Bron
Nationaal Trial Register

Verkorte titel
Tracing stem cells after transplantation

Aandoening

Allogeneic hematopoietic stem cell transplantation

Ondersteuning

Primaire sponsor: Princess Máxima Center for Pediatric Oncology
Overige ondersteuning: Princess Máxima Center for Pediatric Oncology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study endpoints are: (1) The total number of somatic mutations acquired after HSCT in the HSCT recipient and his/her donor; (2) The frequency of HSC clones contributing to production of each of the mature blood lineages in the HSCT recipient and donor.

Toelichting onderzoek

Achtergrond van het onderzoek

Hematopoietic stem cell transplantation (HSCT) is a last-resort curative therapy for patients suffering from various, otherwise lethal, diseases. The success of this therapy relies critically on adminstration of sufficient numbers of donor HSCs. However, due to lack of strategies to count and trace human HSCs, the number of engrafting HSCs and their long-term contribution to hematopoiesis remain elusive.

Here, we will use innovative technology, which employs single-cell analysis of naturally occurring genetic mutations to retrospectively reconstruct the number of HSCs clones, their quantitative contributions to each of the mature blood lineages and their mutational burden in human allo-HSCT recipients and their donors.

This is a fundamental, observational study. We will include 10 HSCT recipients transplanted at pediatric age, and their healthy donors. The study intervention is a single blood collection of 10 mL venous blood.

Doel van het onderzoek

Hematopoiesis after transplantation is supported by a limited number of HSCs, and the proliferative stress posed upon these cells compromises their long-term genomic and functional integrity,

Onderzoeksopzet

One randomly selected time point after HSCT

Onderzoeksproduct en/of interventie

N/a

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

(1) Allogeneic HSCT with bone marrow cells from a healthy sibling donor; (2) Age at HSCT <18 yrs; (3) First HSCT; (4) Availability of viably frozen donor bone marrow cells from the Biobank of the UMC Utrecht; (5) >95% donor chimerism; (6) No major HSCT-related complications (see exclusion criteria).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

(1) Major HSCT-related complications, such as >grade 2 graft versus host disease; (2) Secondary graft failure; (3) Objection to be notified about actionable findings from whole-genome sequencing; (4) Failure of the HSCT recipient, donor and/or their legal representatives to understand the patient information and informed consent form (either due to intellectual disability or to language problems). Of note: Only include subjects in whom both the HSCT recipient and his/her donor (and, if applicable, their caregivers) agree to participate in the current study are eligible.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2019
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54736
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7585
CCMO	NL68140.041.19
OMON	NL-OMON54736

Resultaten