Long-term hematopoiesis in transplantation survivors

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Hematopoietic stem cell transplantation (HSCT) is a last-resort, curative therapy for patients suffering from various, otherwise lethal, diseases. Due to improved treatment strategies, the number of HSCT survivors and their life expectancy continue...

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

Samenvatting

ID

NL-OMON20624

Bron
Nationaal Trial Register

Verkorte titel
Long-term HIT

Aandoening

Allogeneic Hematopoietic Stem Cell Transplantation

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Determine the percentage of HSCT survivors with hematopoietic dysfunction, defined as: (1) cytopenia; (2) clonal hematopoiesis; (3) loss of donor chimerism; (4) bone marrow failure; (5)

myelodysplasia; and (6) donor-cell leukemia.

Toelichting onderzoek

Achtergrond van het onderzoek

This is an observational, explorative study, embedded in the HSCT LATER outpatient clinic of the Princess Máxima Center. The study visit will be combined with a clinical visit, as part of regular post-HSCT follow-up. All participants will undergo clinical assessment of HSCT-related long-term effects by a trained physician, including measurement of differential blood counts, as part of routine clinical care. For this study, we will use these clinical data, and collect an additional blood sample for in-depth assessment of hematopoietic integrity after HSCT.

Doel van het onderzoek

Hematopoietic stem cell transplantation (HSCT) is a last-resort, curative therapy for patients suffering from various, otherwise lethal, diseases. Due to improved treatment strategies, the number of HSCT survivors and their life expectancy continue to increase1. In pediatric HSCT survivors, the donor stem cells may have to live far beyond the normal human life span2. It remains unknown whether transplanted HSCs can sustain life-long healthy blood production in these recipients. In the current project, we hypothesize that HSCT compromises HSC longevity and predisposes to (age-related) hematopoietic dysfunction in the recipient.

Onderzoeksopzet

Single collection of peripheral blood >5 years after HSCT

Onderzoeksproduct en/of interventie

From each HSCT survivor, we will collect up to 50 mL peripheral blood. For participants <25 kg, the volume of blood will be adjusted to 2 mL per kg bodyweight (2.5% of total blood volume).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Underwent allogeneic HSCT at age ≤18 yrs
- A minimum survival of 5 years after HSCT. In case a patient has received multiple HSCTs, the last HSCT will be used to determine this 5-year minimum.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Recipients of a “NiCord” HSCT. NiCord is a clinical trial on the safety and efficacy of transplantation of ex vivo expanded cord blood HSCs. As outcome measures of our study overlap with the outcome of this trial, NiCord recipients will be excluded.
- Failure of the HSCT recipient and/or their legal representatives to understand the patient information and informed consent form (either due to intellectual disability or to language problems).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54142
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9587
CCMO	NL77721.041.21
OMON	NL-OMON54142

Resultaten