Umbilical cord blood transplantation in high-risk hematological patients using stemregenin-1 expanded hematopoietic stem cells.
A feasibility study focusing on engraftment and hematopoietic recovery.

Gepubliceerd: 26-01-2017 Laatst bijgewerkt: 18-08-2022

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26058

Bron
Nationaal Trial Register

Verkorte titel
CORDEX

Aandoening

single cord blood transplantation
stemregenin-1 expanded hematopoietic stem cells
engraftment

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Feasibility as defined by, and to be achieved in ≥ 80% of (evaluable) patients:
1. SR-1 mediated expansion, resulting in > 20-fold expansion of CD34+ cells, and
2. effective hematopoietic (neutrophils > 0.5 x 109/L) engraftment within 30 days upon transplantation

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Insufficient hematopoietic recovery following UCBT is considered to be primarily due to the low number of hematopoietic stem cells in UCB grafts. In-vitro stem cell expansion can be achieved by SCF, Flt3L, TPO and Stemregenin-1 (SR-1). Transplantation of double UCBT including one SR-1 expanded unit was recently demonstrated feasible and safe. The present study aims to evaluate feasibility, engraftment and recovery following transplantation of one expanded unit.

Study objectives:

 To study the feasibility of single UCBT with one ex-vivo SR-1 expanded unit

 To assess side effects and TRM after single UCBT with one expanded unit

 To assess engraftment and engraftment kinetics; to evaluate immune reconstitution, acute and chronic GVHD, chimerism, toxicity, progression-free survival and overall survival after single UCBT with one expanded unit.

Intervention:

Patients are treated with a reduced-intensity conditioning regimen, irrespective of patient age, followed by single UCBT, using one SR-1 expanded unit. Post grafting immunosuppression is performed by mycophenolate mofetil (30 days) and cyclosporine A (90

days, taper thereafter)

Duration of treatment:

Patients will be treated with a conditioning regimen during 7 days, followed by transplantation. Subsequent immunosuppression may take up to 180 days.

Patients will be followed until 5 years after registration

Expected duration of accrual: 1 year

Main study endpoint:

Feasibility as defined by, and to be achieved in ≥ 80% of (evaluable) patients:

1. SR-1 mediated expansion, resulting in > 20-fold expansion of CD34+ cells, and

2. effective hematopoietic (neutrophils > 0.5 x 109/L) engraftment within 30 days upon transplantation

Benefit and nature and extent of the burden and risks associated with participation

Benefits for individual patients may include a faster and better hematopoietic recovery, less opportunistic infections after transplantation and less graft versus host disease as compared to double UCBT

Risks of participation include graft failure and autologous recovery

Planned interim analysis and DSMB

An interim analysis will take place after the first 5 patients have been included and are found to be eligible and will be discussed with the DSMB.

Onderzoeksopzet

 At entry: within 30 days before start of treatment

 After 1, 2, 3, 6, 12 and 24 months after transplantation and yearly therafter

Onderzoeksproduct en/of interventie

Patients are treated with a reduced-intensity conditioning regimen, irrespective of patient

age, followed by single UCBT, using one SR-1 expanded unit. Post grafting immunosuppression is performed by mycophenolate mofetil (30 days) and cyclosporine A (90 days, taper thereafter)1.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 18-70 years inclusive

- Diagnosis of poor-risk hematological malignancy and meeting the criteria for a MUD allo SCT

- Lacking a sufficiently matched volunteer unrelated donor or lacking such a donor within the required time period of ≤ 2 months in case of urgently needed alloSCT

- Availability of 1 (≥5/6) matched UCB graft with a nuclear cell count > 2,7 x 107/kg (see paragraph 8.2).

- Availability of an back-up autograft, harvested and frozen earlier in the course of treatment, (harvest according to local aphersis policies)

- WHO performance status 0-2

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Bilirubin and/or transaminases > 2.5 x normal value

- Creatinine clearance < 40 ml/min

- Cardiac dysfunction as defined by:

Reduced left ventricular function with an ejection fraction < 45% as measured by MUGA scan or echocardiogram (another method for measuring cardiac function is acceptable)

Unstable angina

Unstable cardiac arrhythmias

- Pulmonary function test with VC, FEV1 and/ or DCO < 50%

- Active, uncontrolled infection

- History of high dose (≥ 8 Gy) total body irradiation

- Pregnant or lactating females

- HIV positivity

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-03-2017
Aantal proefpersonen:	10
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	26-01-2017
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	NL6082
NTR-old	NTR6229
Ander register	METC Erasmus MC : MEC 2016-689

Resultaten