Potential HIV Cure by Stem Cell Transplantation

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To gain insight in clinical, virological and immunological mechanisms and predictors of the eradication of HIV. To gain insight in the dynamics of the T cell HIV reservoir in which HIV is persisting. To gain insight in different levels of immune...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Leukaemias
Study type	Observational invasive

Summary

ID

NL-OMON45224

Source
ToetsingOnline

Brief title
IciStem

Condition

- Leukaemias
- Immunodeficiency syndromes
- Viral infectious disorders

Synonym
AIDS, HIV

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: amfAR

Intervention

Keyword: hiv eradication, stem cel transplantation

Outcome measures

Primary outcome

Description of clinical, virological and immunological data before and after transplantation. Assessment of HIV integration sites to determine whether residual HIV derives from a long lived latent infected cell or from cell proliferation. Assessment of TRECs to distinguish between recent thymic emigrant and the peripheral T cell pool.

Secondary outcome

Assessment of different levels of immune responses

Study description

Background summary

The implementation of combination antiretroviral therapy (cART) has substantially reduced AIDS-related morbidity and mortality. cART is unable to eliminate HIV due to viral persistence of HIV in latent reservoirs and therefore patients require life-long daily therapy. Current research is directed at innovative approaches beyond cART towards eradication of the latent HIV reservoir and cure of infection. The only medical intervention that has successfully been able to cure HIV was in the Berlin patient by an allogeneic hematopoietic stem cell transplantation (alloHSCT) with a donor who carried a HIV-resistance gene (defect in the CCR5 co-receptor of HIV). Since this success, HIV infected patients requiring a HSCT are of particular interest for the research community.

Study objective

To gain insight in clinical, virological and immunological mechanisms and predictors of the eradication of HIV. To gain insight in the dynamics of the T cell HIV reservoir in which HIV is persisting. To gain insight in different

levels of immune responses before and after HSCT.

Study design

Observational case study of two years.

Study burden and risks

The benefits are a direct and valuable contribution to the knowledge regarding HIV persistence and cure. Additionally, all finding that could support clinical decision making will be reported to treating physicians. Risks and burden are minor since all blood draws are combined with blood sampling for clinical indications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Stemcel transplantation on clinical indication
HIV infected
18 years old

Exclusion criteria

Any patient unable to give informed consent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-04-2015
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO Date:	14-04-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-11-2017
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL53114.041.15