Obtaining Leukapheresis-derived Product from HIV-Infected Individuals

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testing and validation of the procedures for the collection and the transport to the laboratory of the sponsor in the US (VIRxSYS, Gaithersburg, MD) of PBMC's donated via leukapheresis by HIV-1 infected persons in the Netherlands and the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON30530

Source
ToetsingOnline

Brief title
VRX496-EUR-06-003

Condition

- Viral infectious disorders

Synonym
HIV-1 infection, HIV-seropositivity

Research involving
Human

Sponsors and support

Primary sponsor: VIRxSYS
Source(s) of monetary or material Support: betaald door de sponsor van het onderzoek (zie vraag B6)

Intervention

Keyword: anti-sense RNA, cell therapy, HIV-1 infection, leukapheresis

Outcome measures

Primary outcome

Number of leukapheresis products successfully collected from the subjects in the Netherlands and transported to the United States; number of viable CD4+ T cells per leukapheresis product; for each leukapheresis product, the percentage of CD4+ T cells successfully transduced; for each leukapheresis product, the expansion of CD4+ T cells achieved; for each leukapheresis product, the post-cryopreservation viability of the expanded cells.

Secondary outcome

Any logistical or technical problems identified from the time the harvested cells leave the body of the donor to the time the primary measures of outcome are made will be documented.

Study description

Background summary

Even is antiretroviral therapy (ART) has improved the treatment of HIV-1-infection dramatically, the life long therapy and its side effects make it b=necessary to look for other treatment options. Treatment that protects CD4+ T cells against infection with HIV-1 might be beneficial. A possibility is to modify the CD4+ T cells with a viral vector that expresses an anti-sense RNA directed against HIV-1. It has been shown that these modified CD4+ T cells inhibit HIV-1 replication effectively. To perform this strategy, enough CD4+ T cells have to be taken out a patient and have to be transported to the laboratory in order to transduce them with the vector. The company VIRxSYS, the sponsor of the study, is capable to perform this procedure. It is important to examine the feasibility of the leukapheresis procedure (to harvest the CD4+ T cells), the feasibility of the transport and the effect of the transport of the

cells to the laboratory before applying the whole treatment. In this study, the participants will undergo a leukapheresis procedure to harvest the cells, after which the cells will be transported to the laboratory of the sponsor in the USA.. The (modified) CD4+ T cells will not be shipped back to the study site in the Netherlands and will not be given back to the participants. The results of this study will be important to conduct the study in which the treatment with the modified CD4+ T cells will be applied.

Study objective

testing and validation of the procedures for the collection and the transport to the laboratory of the sponsor in the US (VIRxSYS, Gaithersburg, MD) of PBMC's donated via leukapheresis by HIV-1 infected persons in the Netherlands and the conformation that the laboratory processes for the treatment, modification, the replication and Cryopreservation of these PBMCs are good enough for the therapeutic intervention.

Study design

Prospective observational single center study.

Study burden and risks

There are 3 study visits, which take time and effort for the participants. The leukapheresis (2nd visit) takes 4 hours and, even if it is a standard procedure that is used very frequently and which is generally very safe, there is a small risk for the participant of: irritation, swelling or bruising on the site of insertion, nausea, vomiting, epileptic insults, blood loss, infection, skin rash, flushing, hives, numbness and tingling, edema, anaphylactic reaction. Also the blood draws are a small risk: pain, bruising, lightheadedness, infection.

Contacts

Public
VIRxSYS

200 Perry Parkway
MD 20877 Gaithersburg
Verenigde Staten
Scientific
VIRxSYS

200 Perry Parkway

MD 20877 Gaithersburg
Verenigde Staten

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age 18 years or older;
- able and willing to provide informed consent;
- proven HIV-1-infection;
- good general health;
- CD4+ T-cell count 350 cells/mm3 or higher;
- plasma HIV-1 RNA 5000 copies/mL or higher;
- veins suitable for leukapheresis;
- willing to undergo the leukapheresis procedure, which takes up to 4 hours at clinic;
- body weight over 55 kg.

Exclusion criteria

- earlier treatment with antiretroviral therapy more than 7 days;
- any symptoms, now or in the past, of active or unstable cardiovascular disease (unless treating physician approves participation);
- systolic blood pressure below 100 mm Hg, or systolic blood pressure erect more than 20 mm Hg lower than supine;
- symptoms, now or in the past, of a coagulation disorder;
- subject is pregnant or breast-feeding;
- Laboratory tests for hemoglobin, white blood cells, platelets, renal and liver function outside certain limits.
- use of anti-coagulant medication in the two weeks prior to the scheduled leukapheresis, such as Aspirin, dypiridamole, or warfarin;
- any serious illness requiring treatment and/or hospitalization within 30 days prior to study

participation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL15758.018.06