Maraviroc Immune Recovery Study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24984

Source
NTR

Brief title
MIRS

Health condition

HIV

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Pfizer

Intervention

Outcome measures

Primary outcome

30% increase in CD4 cell count compared with placebo.

Secondary outcome

Changes in plasma HIV RNA.

Study description

Background summary

SUMMARY

Rationale:

Improving cellular immunity by means of increasing CD4 cells is one of the goals of antiretroviral therapy in HIV, which is achieved by means of virological suppression. A certain group of patients, the so called “immunologic non responders”, fail to reach an acceptable CD4 cell increase despite an adequate virologic response on antiretroviral treatment. Recently a new antiretroviral agent, maraviroc (Celsentry®), is registered for the treatment of patients infected with CCR5 tropic HIV-1 virus. However, data is available suggesting that treatment with maraviroc leads to immune recovery (increase in CD4 cells) in patients who are infected with dual/mixed tropic HIV-1 virus, in the absence of a virologic response. This suggests an alternative mechanism for immune recovery, which could be especially beneficial for this group of patients.

Objective:

The primary objective is to confirm the hypothesis that maraviroc stimulates immune recovery; the secondary objective is to explore, by virologic and immunologic investigations, the underlying mechanisms of this hypothesis.

Study design:

multicentre, randomized, placebo-controlled, double blind, exploratory mechanistic study.

Study population:

HIV-1 infected patients 18 years or older, who meet the inclusion criteria.

Intervention (if applicable):

One group receives maraviroc (dose dependent on co-medication), the other group placebo.

Main study parameters/endpoints:

A 30% increase in CD4 cell rise in the treatment group (compared with placebo).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

1. In the treatment group subjects will start with a registered antiretroviral agent (maraviroc).

2. During the treatment year patients will perform several study visits, probably three more compared with regular visits on the outpatient clinic.

3. Each visit, blood will be drawn by venapuncture for immunologic and virologic investigations (see flow chart).

Study objective

Maraviroc, by a yet unknown mechanism, stimulates immune recovery by increasing CD4+ cell count.

Study design

Screening, baseline, week 2,4,8,12,24,36,48.

Intervention

Study subjects will receive either maraviroc or placebo.

Contacts

Public
Universitair Medisch Centrum Utrecht
Postbus 85500

Huispostnummer F.02.126
088-7555555, sein 3811
S. Lelyveld, van
D.I.G.D., afdeling Interne Geneeskunde & Infectieziekten

Utrecht 3508 GA
The Netherlands
Scientific
Universitair Medisch Centrum Utrecht
Postbus 85500

Huispostnummer F.02.126
088-7555555, sein 3811
S. Lelyveld, van
D.I.G.D., afdeling Interne Geneeskunde & Infectieziekten
Utrecht 3508 GA
The Netherlands

Eligibility criteria

Inclusion criteria

1. Age 18 years or older;

2. HAART with a maximal treatment interruption of two weeks;

3. viral suppression (< 50 copies/ml) for 6 months.

And either:

CD4+ count < 200 cells/microl after minimal one year of treatment with HAART (study group one).

Or:

a CD4+ cell count between 200 and 350 cells/microl after minimal two years of treatment with HAART (studygroup two).

Exclusion criteria

1. HAART consisting of a combination of tenofovir and didanosine;

2. Active infection for which antimicrobial treatment;

3. Acute hepatitis B or C;

4. Chronic hepatitis B or C for which treatment with (peg)interferon and/or ribavirine;

(Note: patients with untreated chronic hepatitis B or C can be included);

5. Immunosuppressive medication;

6. Radiotherapy or chemotherapy in the past 2 years;

7. Pregnancy or breastfeeding an infant;

8. Subjects with known hypersensitivity to maraviroc or to peanuts, or any of its excipients or dyes as follows:

a. Excipiens from tablet: microcrystalline cellulose, dibasic calcium phosphate (anhydrous), sodium starch glycolate, magnesium stearate.

b. Film-coat: [Opadry II Blue (85G20583) contains FD&C blue #2 aluminium lake, soya lecithin, polyethylene glycol (macrogol 3350), polyvinyl alcohol, talc and titanium dioxide.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	130
Type:	Anticipated

Ethics review

Positive opinion
Date: 15-12-2008
Application type: First submission

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
NTR-new	NL1521
NTR-old	NTR1592
Other	NL24441.041.08 : 2008-003635-20
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A