Maraviroc Immune Recovery Study (MIRS): A multicentre, randomized, placebo-controlled, exploratory mechanistic study into the role of Maraviroc on immune recovery

Published: 10-10-2008
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The primary objective is to confirm the hypothesis that Maraviroc stimulates immune recovery; the ssecondary objective is to explore, by virologic and immunologic investigations, the underlying mechanisms of this hypothesis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON35447

Source
ToetsingOnline

Brief title
MIRS

Condition

- Viral infectious disorders

Synonym
HIV, human immunodeficiency virus

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Pfizer,subsidie fabrikant maraviroc (Pfizer Inc.)

Intervention

Keyword: CD4, HIV, Maraviroc

Outcome measures

Primary outcome

A 30% increase in CD4 cell rise in the treatment group (compared with placebo).

Secondary outcome

not applicable.

Study description

Background summary

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.

Study objective

The primary objective is to confirm the hypothesis that Maraviroc stimulates immune recovery; the ssecondary objective is to explore, by virologic and

immunologic investigations, the underlying mechanisms of this hypothesis.

Study design

Double blind placebo controlled trial.

Intervention

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

Patients of UMC Utrecht who participate in research with deuterium oxide ('heavy water') will be asked to drink deuterium oxide.

Study burden and risks

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).
4. Patients of UMC Utrecht who participate in research with deuterium oxide ('heavy water') will be asked to drink deuterium oxide. Also, extra blood will be taken by venapunctions in these patients and urine analysis will be performed.

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

-Age 18 years or older
-HAART with a maximal treatment interruption of two weeks
-viral suppression (< 50 copies/ml) for 6 months;And either:
-CD+ 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

-Previous use of maraviroc
-HIV-2 infection
-HAART consisting of a combination of tenofovir and didanosine
-Active infection for which antimicrobial treatment
-Acute hepatitis B or C
-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)
-Immunosuppressive medication
-Radiotherapy or chemotherapy in the past 2 years
-Pregnancy or breastfeeding an infant
-Subjects with known hypersensitivity to Maraviroc or to peanuts, or any of its excipients or dyes as follows:
• Excipiens from tablet: microcrystalline cellulose, dibasic calcium phosphate (anhydrous), sodium starch glycolate, magnesium stearate.
• 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 phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2009
Enrollment:	130
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Celsentri
Generic name:	maraviroc
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	10-10-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-11-2008
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-07-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-08-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-11-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-01-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-01-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-01-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-02-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-10-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-10-2010
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-10-2012
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
EudraCT	EUCTR2008-003635-20-NL
CCMO	NL24441.041.08