Efficacy and pharmacokinetics of a switch from a regimen consisting of emtricitabine, nevirapine and tenofovir to rilpivirine, emtricitabine and tenofovir in virologically suppressed HIV-1 infected patients.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26054

Source
Nationaal Trial Register

Brief title
Rilpivirine switch study

Health condition

HIV

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Gilead Sciences

Intervention

Outcome measures

Primary outcome

Number of subjects with HIV-1 RNA <50 c/mL at Week 12 (ITT population, snapshot analysis).

Secondary outcome

1. Cmin RPV levels in patients that switch from NVP to RPV at 1, 2, 4, 6, 8, 12 and 24 weeks in comparison with Cmin observed in fase III RPV trial;

2. Number of subjects with HIV-1 RNA <50 c/mL at Week 24 and 48 post-switch (ITT population, snapshot analysis).

Study description

Background summary

Rationale:

Patients treated for HIV often have to switch from one antiretroviral (ARV) to another for side effects. Nevirapine (NVP) is an
ARV used for the treatment of HIV infected patients. It is a strong
inducer of CYP3A4. Rilpivirine (RPV) is a new ARV that has shown efficacy
and excellent tolerability in 2 recent phase III clinical trials. It is
also metabolised through a CYP3A4 pathway. This study will evaluate the
impact of NVP CYP3A4 induction on the pharmacokinetics (PK) of RPV when
patients switch from NVP to RPV. Furthermore, the safety of a switch from
NVP to RPV will be evaluated.

Objective:

To evaluate the safety of a switch from NVP to RPV. To measure
the impact of NVP CYP 3A4 induction on Cmin serum levels of RPV when
patients switch therapy from NVP to RPV. For this goal RPV trough
concentrations will be compared with the mean Cmin of 80 ng/ml observed in
2 phase III trials in which RPV 25mg qd was given to treatment naïve HIV-
1 infected patients.

Study design:

This is a single arm intervention study.

Study population:

50 adult HIV-1 infected patients treated with NVP, emtricitabine (FTC) and tenofovir (TDF) with an undetectable HIV plasma viral load for 6 months will switch from TDF, FTC, NVP to TDF, FTC, RPV 25mg qd. This latter treatment will be given as a single tablet regimen (Eviplera®) that includes FTC, TDF and RPV.

Intervention: Switch from NVP to RPV.

Main study parameters/endpoints:

Primary endpoint: Number of subjects with HIV-1 RNA <50 c/mL at Week 12 (ITT population, snapshot analysis).

Secondary endpoint: Cmin RPV levels in patients that switch from NVP to RPV at 1, 2, 4, 6, 8, 12 and 24 weeks in comparison with Cmin observed in fase III RPV trial. Number of subjects with HIV-1 RNA <50 c/mL at Week 24 and 48 post-switch (ITT population, snapshot analysis).

Study objective

1. Switching from a nevirapine based HAART regimen to a rilpivirine based HAART regimen is save in patients with undetectable plasma HIV RNA at the time of switch;

2. Nevirapine induces the CYP3A4 mediated metabolism of rilpivirine.

Study design

12, 24, 48 for HIV RNA plasma load assessment;

1, 2, 3, 4, 8 weeks for PK assessment.

Intervention

Switch from nevirapine to Eviplera® (=rilpivirine, emtricitabine, tenofovir) in patients treated with nevirapine, tenofovir and emtricitabine.

Contacts

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Eligibility criteria

Inclusion criteria

1. Able to take medication with a 500 kcal meal;

2. Treated with NVP, FTC, TDF for at least the last 9 months;

3. No history of HIV virologic failure;

4. The last 2 measured HIV-RNA levels in plasma were <50 copies/ml;

5. ≥6 months between the first and last plasma with <50 copies/ HIV RNA/ml.

Exclusion criteria

1. Use of proton pump inhibitors;

2. Use of H2-antagonists.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2012
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 39388
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3216
NTR-old	NTR3368
CCMO	NL40306.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39388

Study results

Summary results
N/A