Switching to rilpivirine

Rilpivirine (Edurant) is an anti-HIV drug called a non-nuke that is generally better tolerated than its chemical cousin efavirenz (Sustiva and in Atripla). Rilpivirine, together with the following drugs, is sold in one pill called Complera:

- tenofovir (Viread)
- FTC (emtricitabine, Emtriva)

Doctors in the U.S. conducted a study called Spirit, whereby HIV-positive volunteers who were already using a regimen based on a protease inhibitor boosted with ritonavir (Norvir) were randomly assigned to one of the following treatment groups:

- continue with their existing regimen
- switch to Complera

Six months after the study started, statistical analysis found that Complera was roughly equivalent in effectiveness to a ritonavir-boosted regimen.

Study details

Researchers in the U.S. and a few other countries randomly assigned 476 ART users in a 2:1 ratio to the following:

- Complera
- continue with their existing regimen

The average profile of participants at the start of the study was as follows:

- 88% men, 12% women
- age – 43 years
- duration on ART – three years
- CD4+ count – 580 cells
- viral load – 50 copies/ml

Commonly used drugs at the start of the study included the following:

- Truvada (tenofovir + FTC)
- Kivexa (abacavir + 3TC)
- atazanavir (Reyataz)
- lopinavir (in Kaletra)
- darunavir (Prezista)

Results - After 24 weeks

The proportion of participants whose viral load was less than 50 copies/ml at week 24 of the study was as follows:

- Complera – 94%
- ritonavir-boosted protease inhibitor regimen – 90%

Changes in CD4+ cell counts were as follows:

- Complera – an increase of 20 CD4+ cells
- ritonavir-based protease inhibitor regimen – an increase of 32 CD4+ cells
These differences in viral load and CD4+ cell counts were not statistically significant. Therefore, the Spirit analysis found that switching patients from a ritonavir-boosted regimen to Complera was roughly equivalent in effectiveness to maintaining them on a ritonavir-boosted regimen. The technical statistical term for this is “non-inferior.”

**Mutations**

HIV can develop a change, or mutation, in its genetic makeup called K103N when exposed to insufficient levels of non-nukes such as nevirapine (Viramune), efavirenz and delavirdine (Rescriptor). This mutation makes it easier for HIV to escape the effects of non-nukes, including rilpivirine. However, in the present study, among the 17 participants (5%) who had this mutation and who received rilpivirine, all were able to keep their viral loads suppressed.

**Complications and side effects**

Severe or life-threatening adverse events were distributed as follows:

- Complera – 5%
- ritonavir-boosted PI regimen – 7%

Unfortunately, researchers did not present a detailed list of specific adverse events that occurred.

Severe or life-threatening changes in lab tests were distributed as follows:

- Complera – 6%
- ritonavir-boosted PI regimen – 11%

These included elevated levels of the following proteins in the blood:

- enzymes – creatine kinase and AST
- waste product – bilirubin

**Changes in lipid levels**

Generally, participants who switched to Complera had significant decreases in the following fatty substances in their blood:

- total cholesterol
- LDL-cholesterol (so-called bad cholesterol)
- triglycerides

These changes were statistically significant.

Moreover, the change in the ratio of total cholesterol to HDL-cholesterol (so-called good cholesterol) among participants was generally favourable among those who received Complera. In theory, these changes should reduce a person’s chances of a heart attack in the future.

**Changes in kidney health**

The kidneys filter blood, sending waste into urine and returning nutrients and other vital substances back to the blood.

A relatively simple way of assessing kidney health is to conduct blood and urine tests and use these to estimate the rate at which the kidneys are able to filter wastes. This is called the estimated glomerular filtration rate (eGFR). Healthy kidneys should have an eGFR greater than 90. In the present study, the eGFR fell very slightly from 109 to 105 among Complera users and remained steady at 109 among people who continued to use ritonavir-boosted regimens.

**Summary**

Switching participants from a ritonavir-based PI regimen that contained ritonavir to Complera was roughly equal in
effectiveness. Moreover, favourable changes in cholesterol and other lipids occurred among Complera users.

—Sean R. Hosein

REFERENCE:

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Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

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