A trial of Kaletra monotherapy

Researchers at several clinics in Spain recruited 205 HIV positive volunteers (20% female, 80% male) for a trial of monotherapy with lopinavir/r (Kaletra). The average profile of participants was as follows:

- age – 42 years
- CD4+ count – 474 cells
- 45% previously had symptoms of AIDS

Before entering this study, all volunteers had been taking lopinavir/r and either two nucleosides analogues or one nuke and one nucleotide analogue (tenofovir, Viread). As a result, their viral loads had been suppressed below the 50-copy mark for about a year and a half.

Once in the study, participants were randomly assigned to be in one of the following arms, or groups:

- continuing their existing lopinavir/r regimens (triple therapy)
- simplifying their regimen to only lopinavir/r (monotherapy)

Researchers reported results after one year.

Results—effectiveness

After one year, the proportion of participants in each group whose viral load was consistently below the 50-copy mark was as follows:

- triple therapy – 90%
- monotherapy – 85%

This difference was not statistically significant and suggests that monotherapy is not less effective than triple therapy.

Changes in CD4+ cell counts were as follows:

- triple therapy – 31 extra CD4+ cells
- monotherapy – 65 extra CD4+ cells

Again, this difference was not statistically significant.

Results—rising viral load

In six participants on monotherapy, viral load rose above the 50-copy mark and this increase was sustained. Doctors added nucleoside analogues to their regimens, and four of the six participants had their viral load fall below the 50-copy mark and remain there.

In the triple-therapy group, three participants had the same problem and their regimens had to be changed entirely.

Results—resistance

Partial resistance to protease inhibitors was detected in three participants taking monotherapy and one participant on triple therapy. In two cases of this type of resistance, doctors were able to switch participants to combinations that included saquinavir (Invirase)/ritonavir and successfully re-suppress their viral load. We do not have details about the other participants.
**Side effects**

In three cases, side effects were so severe that participants left the study, as follows:

- diarrhea - two people
- difficulty falling asleep - one person

No one left the monotherapy group due to side effects.

**Abnormal lab tests**

There were no significant differences between the two study groups when lab test results were compared, particularly tests involving lipids (cholesterol and triglycerides).

Severely elevated levels of triglycerides were detected in 10% of participants taking monotherapy and 4% of participants on triple therapy.

Six cases of very high levels of liver enzymes (AST and ALT) were detected during the study. In five of these cases, researchers suspected that hepatitis C virus co-infection was responsible for the increase in AST and ALT.

Overall, results from this study suggest the possibility that monotherapy with lopinavir/r can help keep HIV suppressed in some HIV positive people. However, longer studies are needed so that the effectiveness and sustainability of this unusual therapy can be assessed. Further notes on this and related studies appear in the following story.

**REFERENCE:**

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