Darunavir-ritonavir monotherapy—impact on fat and bones

Darunavir is a powerful protease inhibitor. In a previous trial called Monet, results showed that switching to darunavir-ritonavir monotherapy from standard triple therapy (ART) is roughly as effective as ART.

The Monarch study

In a substudy of a trial called Monarch, Italian researchers recruited 30 HIV-positive participants who were taking potent combination therapy for HIV (commonly called ART or HAART) and had low viral loads (less than 40 copies/ml) and randomly assigned them to change their regimens to one of the following:

- darunavir 800 mg + ritonavir 100 mg (all drugs once daily)
- darunavir 800 mg + ritonavir 100 mg + Truvada (a fixed-dose combination of tenofovir and FTC)

In the substudy, researchers conducted multiple blood tests and repeated low-dose X-ray scans of participants to assess changes in bone density and distribution of body fat.

Results

The study lasted for 48 weeks and at that time the amount of fat deep in the belly (visceral fat) did not change significantly from the start of the study (baseline). However, all participants saw improvements in the body’s sensitivity to the hormone insulin, which helps to regulate blood sugar levels.

Among participants who received darunavir-ritonavir only, there were small increases in bone mineral density, between 1% and 2%. However, these changes could have arisen because at the start of the study more participants who received darunavir-ritonavir had been taking tenofovir (in Truvada).

Levels of fat in the limbs—a substitute or surrogate for assessing fat in the face (researchers do not want to X-ray the face, as the brain could be affected by radiation)—were stable in all participants during the study.

Among participants in the substudy, there was no mention of changes in viral load—presumably because there were none.

In context

The Monarch study should be considered a well-designed pilot study. Its findings are suggestive and can be used to design a larger and longer study.

—Sean R. Hosein

REFERENCE:

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Production of this content has been made possible through a financial contribution from the Public Health Agency of Canada.

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