Once-a-Month HIV Meds Show Promise in Early Trial

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A pair of long-acting HIV antiretrovirals (ARVs) maintained adequate blood levels and exhibited a promising safety profile when given to HIV-negative participants in an early trial, aidsmap reports. Investigators tested the safety and pharmacokinetics of an injectable nanosuspension of the investigational integrase inhibitor GSK1265744 as well as TMC278-LA, which is a long-acting formulation of Janssen's non-nucleoside reverse transcriptase inhibitor Edurant (rilpivirine). They presented their findings of this Phase I trial of 47 participants at the 7th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2013) in Kuala Lumpur.

A nanosuspended drug exists in tiny crystals that are suspended in liquid, leading to a more drawn-out period during which the drug is active within the body. Their less-frequent dosing is of particular interest for researchers for their use in improving adherence to ARVs, as well as for their use as a pre-exposure prophylaxis (PrEP) HIV prevention drug regimen among people at high risk for contracting the virus.

The study participants all began with two weeks of 30 milligrams per day of oral GSK1265744 to test that drug's safety and tolerability. Then, after a weeklong gap period, they received one injection of 800 mg of the drug. Next, they were randomly divided into four treatment arms, which then received a respective:

1. Injections of 200 mg of GSK1265744 at weeks 4, 8 and 12.
2. Injections of 200 mg of GSK1265744 at weeks 4, 8 and 12, as well as 1,200 mg of TMC278-LA at week 8 and 900 mg at week 12.
3. Injections of 400 mg of GSK1265744 at weeks 4, 8 and 12, as well as 1,200 mg of TMC278-LA at week 8 and 600 mg at week 12.
4. One injection of GSK1265744 at week 12.

Ten participants dropped out of the trial, seven of them during the oral lead-in part of the trial and three others during the injection part.

In each of the treatment arms, the drugs reached a therapeutic level within three days. Both of them remained at high levels for a long period of time—well above 90 percent of the target concentration—and then dropped off slowly.

The drugs proved safe and well-tolerated, with one participant leaving the study during the lead-in phase because of dizziness and another leaving during the injection phase because of rash. Headache was the most common side effect.

To read the aidsmap story, click here.

To read the conference abstract, click here.

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