

RISK OF POOR PREGNANCY OUTCOMES FOR THREE ANTIRETROVIRAL REGIMENS

PROMISE was a clinical trial for pregnant women with HIV. It took place in India and African countries. In part of PROMISE, women were treated with one of three different ARV regimens. Women on one of these regimens had babies born very prematurely (too early) or with very low birth weight compared to the other two regimens. We wanted to test the findings with our participants in the U.S.

WHO PARTICIPATED

The study took place between



4,646 pregnant women with HIV and their infants participated. Some women were in the PHACS SMARTT study. The rest were in a similar study called IMPAACT.

WHAT WE DID

3 regimens tested:

- **TDF/FTC/LPV/r** (tenofovir/emtricitabine/lopinavir/ritonavir)
- **ZDV/3TC/LPV/r** (ziduvodine/lamivudine/lopinavir/ritonavir)
- **TDF/FTC/ATV/r** (tenofovir/emtricitabine/atazanavir/ritonavir (common in U.S.))

We looked at birth outcomes for three specific antiretroviral regimens used during pregnancy.

We looked at premature birth, very premature birth, low birth weight, very low birth weight, stillbirth, and infant death.

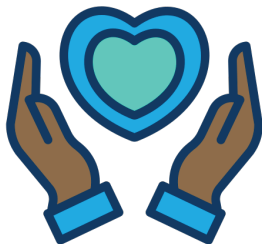
WHAT WE FOUND



The study results in India and Africa suggested that **TDF/FTC/LPV/r** was not safe for pregnant women. But in the U.S., very few women used this regimen. This made it difficult to study this regimen here.

In the U.S., it is more common for pregnant women to take **TDF/FTC/ATV/r**, which contains Tenofovir. We found this one to be as safe as other regimens.

WHAT WE LEARNED



We did not have enough information to evaluate the safety of **TDF/FTC/LPV/r** in the U.S. But because of the findings from the PROMISE study, it may be a good idea to avoid this regimen during pregnancy.

However, other regimens with Tenofovir seem to be safe to use during pregnancy.