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Mulago HIV drug trial disappoints researchers Publish Date: Mar 05, 2013









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By Anne Mugisa and Hillary Bainemigisha

The Long awaited results of the HIV trial done in Uganda, have turned disappointing after the study failed to show any significant effect of the drugs that were being tested.

The results of the trials, which were also done in South Africa and Zimbabwe, were however attributed to the failure of participants to use the drugs as advised.

The results of the Microbicide trial, the Vaginal + Oral Interventions to Control the Epidemic (VOICE), were released Monday at the international Conference on Retroviruses and Opportunistic Infections (CROI) in Atlanta Georgia.

The drugs used in the failed trials included Tenofovir tablets, Tenofovir Gel and Truvada tablets.

322 women in Kampala were enrolled by Makerere University and the John Hopkins University collaboration (MU-JHU) at the Mulago site and given microbicides to test if they could yield the first even women controlled prevention strategy against HIV. Some women were told to insert a vaginal gel and others to swallow tablets of either Tenofovir or Truvada every day.

The study, which was carried out in three African Countries had 5,029 participants selected from the highest risk group. Clinical exams were done every three months as needed and pelvic examinations every six months.

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Results released suggested that the daily use of the drugs did not appear to lessen the risk of HIV infection. On closer analysis, it was discovered that the participants did not adhere to the instructions and most of them did not actually take the drugs.

"It is difficult to know if a product works to prevent HIV if it is not used," the researchers stated adding that the poor adherence affected the study results. Researchers conclude that it was difficult for the younger unmarried women under 25 years to use HIV prevention products daily.

Truvada had been found effective in other studies and was subsequently approved by the US Food and Drug Administration (FDA) for HIV prevention.

The World Health Organisation (WHO) even issued guidance on preventive use of Truvada, encourages countries considering using it to prevent transmission - Pre-Exposure Prophylaxis (PrEP) to do so in the context of demonstration projects. However, the formal implementation guidelines for PrEP are expected in 2015.

The researchers carried out tests that measure the drugs in the body of participants using their blood, vaginal fluids and hair and discovered that the women who actually took the drugs were 29% in the Truvada group, 28% in oral Tenofovir group and 23% in the Tenofovir Gel group.

Dr Clemensia Nakabiito, the study coordinator at Mulago, said the bad news will not stop them from continuing the struggle until a new prevention technology is found. "HIV affects more women and we have to continue looking for a method they can use to protect themselves without necessarily seeking permission from their husbands," she said

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