

“TRUVADA” - ARV PILL TO PREVENT HIV-1

In recent weeks there have been much talk and debate about the oral ARV drug Truvada.

The purpose of this article is to clarify and explain different aspects about the drug Truvada, and how the FDA's (Food and Drug Administration Agency – the statutory agency that approves the use of drugs in the USA) approval of Truvada for prevention of HIV 1 could affect the rest of the World.

If readers have any other question relating to Truvada and not explained in this Article, please do not hesitate to write.

For ease of understanding a Q & A format will be used. Before trying to understand more about Truvada, it is necessary to know about PrEP and PEP.

QUESTION 1: WHAT IS PrEP AND WHAT ARE ITS SIGNIFICANCE

Answer: PrEP, is pre-exposure prophylaxis, in the context of HIV, it is a Drug taken before being exposed to HIV, so that it prevents a person from acquiring HIV when that person is inadvertently exposed to the risks of HIV. Truvada is one such drug approved by FDA for use among some sections of the people who are at a greater risk of being exposed to HIV such as homosexual men (men who have sex with men MSM) who have multiple partners, discordant couples, transgender women and Heterosexual people who are sexually active with multiple partners and who may not be consistent users of condoms. Also Truvada may be considered for IDUs (Intravenous Drug Users) who may not practice safe sex. It is important to note that Truvada is a combination of 2 drugs in a single pill (This will later be explained in greater detail).

QUESTION 2: WHAT IS PEP

Answer: PEP is post exposure prophylaxis, these are ARV's administered after a person has been exposed to HIV or strongly thought to have been exposed to HIV.

These ARV's (combination of 3 drugs) are taken for 21 days, the first dose should be taken before 72 hours, and earlier is better.

There is a 80% chance of not contracting HIV if PEP is taken as prescribed.

The HIV testing time frame for those on PEP is different, its usually a baseline test to ascertain the person on PEP is HIV negative, there will be a test done at 6 weeks, 3 months and then 6 months to ascertain if the individual on PEP has seroconverted or not.

The people who would normally qualify for PEP are medical personnel who may have been directly exposed to HIV during surgical or needle stick injuries from a patient who is HIV positive, Rape Victims, and some times PEP may be considered for discordant couples who may have had a breakage of condom as this may expose the uninfected partner to genital fluids.

In some Western Countries PEP is considered for Homosexual partners who have put themselves at risk of HIV.

QUESTION 3: IS PrEP AND PEP A NEW CONCEPT

ANSWER: No, PrEP and PEP have been there for several years, but the fact that the approval of Truvada as a PrEP for wider use among the population as a preventive drug for HIV 1 is new.

It is the first daily one pill drug that has been approved anywhere in the World to reduce the risk of contracting HIV 1.

QUESTION 4: IS TRUVADA A NEW TYPE OF ARV

ANSWER: No, Truvada has been around for 8 years (since 2004), Truvada is the brand name, it is manufactured by a company called Gilead Sciences, based in Foster City, California USA, it is blue in colour, oblong in shape and has the imprint "GILEAD" on one side of the pill, and on the otherside it has the imprint "701".

Truvada is some times prescribed as one of the many drug combination which HIV positive people who are on HAART (Highly active antiretroviral therapy) take to keep their viral load under control.

QUESTION 5: WHAT IS THE COMPOSITION OF TRUVADA AND HOW DOES IT WORK

ANSWER: Truvada is composed of two antiviral drugs, whose generic names are Emtricitabine (FTC) 200mg and Tenofovir (TDF) 300 mg. Each pill weighs a total of 500mg.

Emtricitabine is from a class of drug called Nucleoside Reverse Transcriptase Inhibitors (NRTI) and Tenofovir is from a class of drug called Nucleotide Reverse Transcriptase Inhibitor (NRTI).

The drug blocks the reverse transcriptase enzyme of HIV from converting the HIV RNA into a HIV DNA, by this way the virus will not be able to complete the HIV life cycle inside of a CD4 cell.

It is important to note that Truvada is a combination of only 2 drugs. It is also important to emphasize that those who are on HAART take 3 drugs called the triple drug cocktail to avoid developing resistance to ARV's, which means that for those who are on HAART, Truvada may form only a part of the triple drug cocktail and should never be considered as a stand alone pill.

However Truvada is approved as PrEP for prevention of HIV for those who are HIV negative, and for such people there will be no need for a triple drug cocktail and Truvada is sufficient.

QUESTION 6: CAN YOU TAKE TRUVADA IF YOU ARE NOT SURE OF YOUR HIV STATUS

ANSWER: No, If you take Truvada and if you happen to be HIV positive, then you will develop resistance to ARV's.

The golden rule for those who are HIV positive is to take a combination of 3 drugs as prescribed. This is to avoid developing resistance, hence it is very important to know ones status.

QUESTION 7: HOW EFFECTIVE IS TRUVADA

ANSWER: Studies have found an overall risk reduction of 90%,if the Truvada pill is taken everyday and exactly as prescribed. Thus Truvada is not 100% effective, hence condom use is recommended even if the person is on PrEP. (Its like driving a car that has an airbag and still the driver is advised to wear the seat belt to offer a double protection incase of an accident).

If truvada is not taken regularly then the protection drops off quickly. Just like any ARV's, adherence to the drug is critical for effectiveness.

Also people on Truvada who are HIV negative have to get retested for HIV every few months. Truvada can't offer guaranteed protection.

QUESTION 8: WHO WOULD BE THE IDEAL CANDIDATES TO QUALIFY FOR TRUVADA

ANSWER: Truvada may be considered as PrEP for discordant couples, who use condoms consistently,truvada could offer a second barrier of protection, in the event of condom breakage.

It is important to note that if one of the partner is HIV positive and is on ARV's then it is likely for the partner to have lower levels of HIV in the blood and this makes transmission less likely.

If you ask, is it possible that the infected partner could transmit HIV despite taking ARV's? the answer is yes, it is possible. Does it happen often?

No, its exceedingly rare. Studies have shown that HIV can still exist in semen even when it can't be found in the blood using PCR techniques.

Truvada is considered for homosexual men, who have multiple partners and who may not be consistant users of condoms, it is important to mention that homosexual acts without protection have a very high risk of HIV transmission due to greater chances of microscopic mucosal tears in the thin epithelial skin layer of the rectum.

Also truvada may be considered for IDU's (Injectable Drug Users) and heterosexual groups who are at higher risk of HIV like sex workers especially for those who may find themselves in a position where they can't demand condom use.

For example in a family the women is not particularly able to ensure condom use consistently and she does not have control in the way in their sexual dynamics ,and he may or may not be on ARVs, but certainly there is no way for her to force him to take those medications, under such situations Truvada might be considered for such women.

QUESTION 9: ARE THERE OTHER USES OF TRUVADA

ANSWER: Yes, Truvada will be a special boon for heterosexual couples where the women is uninfected, and the man has HIV and they want to conceive a child.

Currently the only safe way to do that is a complicated and expensive procedure called sperm washing.

The mans sperm is treaded so its free from the virus (Note: sperms do not have HIV, it's the fluid surrounding the sperm that has HIV) and then the egg is fertilized in a laboratory and implanted in her uterus.

Prescribing Truvada for the woman as a PrEP and to have unprotected sex during the fertile period could help avoid the complicated and expensive sperm washing technique. However such procedures should be under the supervision of a HIV / AIDS specialist.

QUESTION 10: WHAT ARE THE COSTS INVOLVED?

ANSWER: It would cost around 14,000 US Dollars a year for one individual.

QUESTION 11: IS TRUVADA TAKEN WITH OR WITHOUT FOOD

ANSWER: It is one pill a day, taken with or without food.

QUESTION 12: **WHAT ARE THE OTHER IMPLICATIONS OF TAKING TRUVADA**

ANSWER: Truvada by itself is not a complete treatment of HIV infection, if you have HIV or get HIV while taking Truvada you may develop drug resistance which makes the infection harder to treat.

Truvada does not cure HIV or AIDS. Just taking Truvada may not keep you from getting HIV, Truvada does not always prevent HIV infections.

You must practice safe sex at all time, and do not have any kind of sex without protection. You must get tested regularly (at least every 3 months) also you should get tested for other sexually transmitted infections like syphilis and gonorrhea.

QUESTION 13: **WHAT ARE THE CHALLENGES AND CONCERNS WHEN TAKING TRUVADA**

ANSWER: (a) Truvada is an expensive drug and condoms are inexpensive.

(b) It requires regular follow up tests and close monitoring of those who are on Truvada is required.

(c) Truvada is also some times prescribed as part of the triple drug cocktail for those who are HIV positive and who are on HAART, there are fears that too much focus on Truvada as prevention drug may divert attention and funding for those who are on HAART.

(d) Concerns are that once people start taking Truvada, they could increase their risky behavior.

(e) Truvada has to be taken every day regularly, concerns are that will HIV negative people be able to adhere to the drug.

(f) Just like any antibiotic if people don't adhere to the prescription they could develop resistance.

(g) For Truvada as a prevention of HIV 1 has to work, it requires a very efficient outreach system in place.

(h) Is it worth the side effects?

(i) Anyone considering Truvada for prevention would be making a life time commitment to a daily medication regimen.

(j) Truvada is not meant to replace condoms and other safe sex measures, but to be used with them for added protection.

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QUESTION 14: WHAT ARE THE SIDE EFFECTS OF TRUVADA

ANSWER: Common side effects include:

The most common side effects of Truvada when taken with other anti-HIV-1 medicines to treat HIV infection are diarrhea, dizziness, nausea, headache, fatigue, abnormal dreams, sleeping problems, rash, and depression.

In clinical trials of Truvada taken alone for pre-exposure prophylaxis, the most common side effects reported were stomach ache (abdomen) pain, headache and decreased weight.

There are other serious side effects when taking Truvada ,talk to your health care provider to learn more about the side effects of Truvada.

QUESTION 15: IS TRUVADA SAFE DURING PREGNACY

ANSWER: It is not known if Truvada can harm your unborn baby, so speak to your health care provider about the risk of using Truvada while pregnant.

QUESTION 16: HAS THE FDA APPROVRD TRUVADA FOR IDUs

ANSWER: FDA has not reviewed the use of PrEP in other traditionally high risk groups such as IDUs, however according to one study ,oral PrEP can be a part of cost effective intervention package to control HIV epidemic where IDU is significant and where budgets are limited.