

HIV and clinical trials

Last updated January 2013/ Due for review January 2015

Clinical trials for people with HIV are currently testing treatments in six broad categories, at all stages of HIV disease:

- Treatments intended to attack HIV at different stages of its lifecycle in order to stop or delay damage to the immune system, exploring and developing different classes of anti-HIV drugs.
- Treatments intended to strengthen the immune system.
- Treatments for side-effects, such as cardiovascular disease.
- Treatments for other conditions often seen in people with HIV.
- Prevention, screening and treatment for sexually transmitted infections and anal and cervical cancer.
- Methods of preventing HIV, such as vaccines.

Advances in HIV therapy

Major advances in HIV therapy have been made as the result of clinical trials. For example:

- The **ACTG 320** study showed that triple therapy with AZT, 3TC and **indinavir** was more likely to prolong life and reduce symptoms than AZT and 3TC alone, for people with CD4 counts below 200.
- Clinical trials help guide the choice of anti-HIV drugs. The **DUET** studies showed that the NNRTI **etravirine** (*Intence*) was effective against HIV that was resistant to other drugs in this class.
- Boosted protease inhibitors are an option for people starting HIV treatment. The **MS98-896** study showed that **lopinavir/ritonavir** (*Kaletra*) achieved more durable suppression of HIV than unboosted **nelfinavir** (*Viracept*). The **POWER** trials showed the newer boosted protease inhibitor **darunavir** (*Prezista*) worked well in people with resistance to other protease inhibitors.
- Some new classes of anti-HIV drugs have recently been developed. For instance, the **BENCHMRK** study showed that **raltegravir** (*Isentress*) was effective in people with a lot of resistance to other anti-HIV drugs, and the **STARTMRK** trial showed that the drug also worked well in people who were starting HIV therapy.

Guiding treatment strategies

Clinical trials have also guided HIV treatment strategies. For example:

- The **SMART** study showed that having a break from HIV treatment meant people were more likely to become ill or to die, compared to people who stayed on treatment all the time. This finding was then confirmed by the **DART** study.
- In the UK it is currently recommended that people start HIV treatment when their CD4 cell count is around 350. This is partly because people in the **SMART** study with CD4 cell counts above this level had lower rates of HIV-related and non-HIV-related illnesses. A large study (called **START**) is currently underway to get a more detailed understanding of the best time to start HIV treatment.

Managing co-infections and other conditions

Clinical trials have also shown how to best manage other conditions that are common in patients with HIV. For example:

- The **APRICOT** study showed that treatment with a combination of pegylated interferon and ribavirin was the best treatment for hepatitis C in people with HIV. Observational studies have shown that people with HIV had better responses to this therapy if they started treatment soon after they were infected with hepatitis C, and because of this early treatment is now recommended.

Preventing mother-to-child transmission

Studies have also been conducted to see how HIV transmission can be prevented, for example from a mother to her baby.

- The **ACTG 076** study showed that AZT treatment during pregnancy, labour and the baby's first weeks of life can reduce the risk of HIV transmission from mother to child by two-thirds.
- The **HIVNET 012** study showed that one dose of **nevirapine** (*Viramune*) taken by a mother during labour reduced the risk of transmission.
- The **Women and Infant Transmission Study** showed that triple-drug treatment during pregnancy reduced rates of mother-to-child transmission to below 1%.

Preventing sexual transmission of HIV

Researchers are also looking at ways of preventing sexual HIV transmission:

- In late 2010, results of the **iPrEX** study in men who have sex with men showed that using pre-exposure prophylaxis (PrEP: HIV-negative people taking antiretroviral drugs before sex to prevent infection) reduced the risk of infection with HIV.
- Also in 2010, the **CAPRISA** trial found that a vaginal microbicide gel containing the anti-HIV drug **tenofovir** (*Viread*) reduced the risk of HIV infection among women who received it by 39%.
- In May 2011, the **HPTN 052** trial closed three years early when it found antiretroviral treatment reduced the risk of HIV transmission from treated partner to uninfected partner by 96%.

How to join a trial

Staff at your clinic may know about trials that are underway or about to start. You could ask your doctor about any research happening that might be appropriate for you to join. There are also several registers, or lists, of trials going on at any time. You could ask at your clinic about how to find these. UK CAB, an HIV advocacy network, also has information on how to find clinical trials:

www.ukcab.net/resources/clinical-trials/finding-clinical-trials/.

If you hear of or read about a trial that interests you, the first step is to talk to the trial's contact person for some more information about the trial.

The staff at the trial centre will usually ask you some questions to check that you meet the basic entry requirements for the trial, and you may have a physical examination and a blood test. After the results of all the tests are available, the trial staff will let you know whether or not you are eligible to take part.

It does not necessarily matter if you are currently receiving treatment at a different clinic or hospital to where the trial is being carried out. But you should tell your regular doctor if you do join a trial at a different centre. You may also want to discuss whether or not to join a trial with your doctor or another member of your clinic team.

Deciding to join a trial

New research cannot lead to reliable findings unless people agree to take part and, by joining a trial, you can contribute to important medical research. But it's important to think carefully about joining a trial. There's a list of possible questions you might want to consider and ask to help you make your decision in our factsheet *Thinking about joining a clinical trial?*

You can find out more about recent research into HIV prevention, treatment and care on www.aidsmap.com.