Earlier this month, the HIV Vaccine Trials Network and the HIV Prevention Trials Network started enrolling volunteers into its new antibody mediated prevention study. Funded by the National Institutes of Health, the antibody these two organisations are starting to test has the power to completely revolutionise the way we prevent new HIV infections in the future.
**SINCE THE BEGINNING** of the HIV/AIDS epidemic in the early 1980s, nearly 39 million people have died from an HIV related infection, and approximately twice that number have been infected with the HIV virus, according to the World Health Organization (WHO).

In the more than 35 years since the virus has been spreading across the planet, leaving devastation in its wake, scientists have been fighting hard to eradicate the menace. Though gains have been made in this time, there is still much to be done, and many have said that the only way to truly take the sting out of the HIV/AIDS epidemic is to create an effective vaccine.

This is the goal of the HIV Vaccine Trials Network (HVTN) – a multidisciplinary team that is facilitating the development of vaccines to prevent HIV/AIDS under the watchful and expert eye of Dr Larry Corey. Early last year, Corey and HVTN joined forces with Dr Myron Cohen and the HIV Prevention Trials Network (HPTN), an international collaborative clinical trials network that develops and tests interventions to see if they are safe and effective at preventing the acquisition and transmission of HIV.

Together these two powerhouses of HIV/AIDS knowledge have begun a quest to use antibody mediated prevention (AMP) as a tool against this disease.

**INTRODUCING THE AMP STUDY**

When infected by a foreign agent, such as bacteria or viruses, the immune system jumps into action. Upon recognising that there is an invader present, the immune system starts to produce antibodies – proteins whose jobs are to seek out and destroy the attacking microscopic forces.

Antibodies are at the heart of Corey, Cohen and their compatriots’ work in a recently launched study affectionately known as the AMP Study. Specifically, the team is looking at an antibody known to the world as VRC01. Laboratory studies have shown that the VRC01 antibody can prevent many different strains of HIV from infecting cells by attaching itself to the virus and neutralising it.

“Fifteen to 20 per cent of people who have HIV have what are called ‘broadly neutralising antibodies’ and a significant number of these antibodies have been isolated in the last few years; VRC01 is a major prototype,” shares Corey. “Our aim is to determine what concentration of this monoclonal antibody for HIV will prevent acquisition of HIV in two separate populations – men who have sex with men, transgender men and transgender women in one study and heterosexual women in another trial.”

In testing this antibody, HVTN and HPTN are taking an inspired approach. Instead of following in the tracks of traditional HIV vaccine studies – in which researchers give people a vaccine and then wait to see if their bodies will make antibodies against HIV in response – the AMP study skips this step. It uses an intravenous infusion to give the antibody directly to the people participating in the trial. Corey expands: “We have had a hard time making a vaccine that has neutralising antibodies. We decided that if we haven’t taught the body yet to make them through a vaccine, we should try delivering them directly”.

**AN INTERNATIONAL COLLABORATION**

The trial, which kicked off in early April, is truly an international endeavour: Looking to test the antibody on groups at high risk of being infected by the virus, the team has called to arms clinics across the globe.

One branch of the study (HVTN 704/HPTN 081) is focusing on the US and South America (Brazil and Peru). It is aiming to enrol participants who identify as men and transgender people who have sex with men. The other branch of the AMP study (HVTN 703/HPTN 081) will mainly focus on participants in sub-Saharan Africa. This arm of the study is specifically focusing on heterosexual women.

The US and South American study is looking to enrol 2,700 participants, while the sub-Saharan Africa study is aiming to enrol 1,500 women. In testing the effectiveness of the antibody, the participants will be split up into three different groups for each study. Following this, one group will receive a high dose of the antibody, the second group will receive a lower dose of the antibody and the final group will receive a placebo.

**AN HIV/AIDS-FREE WORLD**

Though the trials are in their beginning stages – with the second branch of the AMP study to start this month – Corey, Cohen and the team have high hopes for its success. “For me, it is almost like we are beginning the quest for combination antiretroviral therapy,” enthuses Corey – a big statement for him, especially since his work with HIV/AIDS started back in the 1980s when the disease was first discovered in the US. He has seen many ideas come and go in that time.

“When I first started we didn’t have any effective drugs, but then the AZT treatment started, and then we had AZT plus other treatments,” he continues. “However, I think an antibody is better than AZT. Though the AMP study is the first step, it is a hugely promising technology to use antibodies to prevent HIV, like it was to use antiretrovirals to treat HIV for the first time. I just hope the outcome is the same and that it changes the nature of the disease.”
HIV treatment timeline

The milestones for this timeline were provided by www.aids.gov

5 June 1981 – AIDS epidemic officially starts following the release of a report from the US Centers for Disease Control and Prevention (CDC)

November 1983 – Dr Robert Gallo’s lab grows the AIDS virus in immune system cells

19 March 1987 – The FDA approves the first antiretroviral drug, zidovudine (AZT)

24 September 1982 – CDC uses the term AIDS for the first time

9 September 1983 – CDC identifies all major routes of HIV transmission

1985 – The US Food and Drug Administration (FDA) licenses the first commercial blood test, ELISA, to detect antibodies to HIV in the blood

1988 – The World Health Organization (WHO) declares 1 December to be the first World AIDS Day

August 1993 – Two US Federally funded studies are launched on women and HIV/AIDS research: the Women’s Interagency HIV Study and HIV Epidemiology Study

23 December 1994 – The FDA approves an oral HIV test

1994 – AIDS becomes the leading cause of death for all Americans aged 25 to 44

1996 – The FDA approves the first HIV home testing and collection kit; viral load test; and HIV urine test. It also approves the non-nucleoside reverse transcriptase inhibitor (NNRTI) drug, nevirapine

June 1995 – The FDA approves the first protease inhibitor and thus ushers in a new era of highly active antiretroviral therapy (HAART)

1997 – Drug resistance emerges as an area of grave concern within the AIDS community

March 1999 – The biotech company VaxGen begins conducting the first human vaccine trials in Thailand

2000 – Reversing the spread of HIV/AIDS, malaria and tuberculosis becomes a UN Millennium Development Goal

December 2006 – A University of Illinois at Chicago study indicates that medical circumcision of men reduces their risk of acquiring HIV during heterosexual intercourse by 53 per cent

16 July 2012 – The FDA approves the use of Truvada® for pre-exposure prophylaxis (PrEP), meaning that adults at risk of HIV infection due to sexual activity can now take this medication to reduce their risk

2015 – HIV Vaccine Trials Network (HVTN) pairs with HIV Prevention Trials Network (HPTN) to start the Antibody Mediated Prevention (AMP) HIV Prevention Study. The study is testing the idea of giving people antibodies against HIV directly through an infusion. The study will be complete in 2020

2015 – HIV Vaccine Trials Network (HVTN) pairs with HIV Prevention Trials Network (HPTN) to start the Antibody Mediated Prevention (AMP) HIV Prevention Study. The study is testing the idea of giving people antibodies against HIV directly through an infusion. The study will be complete in 2020

20 July 2015 – Researchers report that antiretroviral therapy is highly effective at preventing sexual transmission of HIV from a person living with HIV to an uninfected heterosexual partner

24 February 2003 – VaxGen announces that its AIDSVAX vaccine trial failed to reduce overall HIV infection rates among those who were vaccinated

20 February 2017 – VaxGen announces that its AIDSVAX vaccine trial failed to reduce overall HIV infection rates among those who were vaccinated

24 January 2020 – The FDA approves the use of Truvada® for pre-exposure prophylaxis (PrEP), meaning that adults at risk of HIV infection due to sexual activity can now take this medication to reduce their risk

December 2020 – A study led by scientists at the University of Oxford shows that a new vaccine can prevent HIV transmission

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