

Anti-Aids gel 'brings sexual pleasure'

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By Giordano Stolley

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INDEPENDENT NEWSPAPERS

Professor Helen Rees the executive Director of WRHI - Wits Reproductive Health and HIV Institute. Picture: Jennifer Bruce

Pretoria - Efforts to cut the risk of women contracting HIV could have an interesting side effect - sexual pleasure.

This emerged at the official launch in Pretoria on Tuesday of a 24-month trial of a microbicide gel researchers were hoping would help prevent HIV transmission.

Wits professor Helen Rees (CORR), of the university's reproductive health and HIV institute, said the R300 million trial would involve about 2200 sexually active women at seven locations countrywide.

The Tenofovir gel study - known as Follow-on African Consortium for Tenofovir Studies (Facts) study - would be a follow-up to the Caprisa 004 study, which showed that a highly consistent use of the microbicide by women resulted in a 59 percent reduction in the risk of HIV infection.

Rees said during a previous study involving another gel - that proved unsuccessful in the fight against HIV - participants had noted the gel improved their sexual pleasure.

"One of the big messages we got, was many women said 'We liked this'."

Most of the feedback during that study had come from women in their menopause. If the gel proved successful, the sexual pleasure factor could be a potential marketing option, she said.

But while sexual pleasure might be a positive spin-off, the primary focus of the Facts study would be seeing if it backed up the Caprisa 004 study, which involved a smaller sample of women at only two locations in KwaZulu-Natal.

The Caprisa (Centre for the Aids Programme of Research in South Africa) study began in May 2007, was completed in December 2009, and the data published in March 2010.

The Facts study would see the participants, aged between 18 and 30, using the gel 12 hours before intercourse and within 12 hours after intercourse.

The results of the study were expected to be released by the end of 2013. It was being funded by the science and technology department, the US government and various other organisations, including the Bill and Melinda Gates Foundation.

US ambassador to South Africa Donald Gips announced his country's government would contribute R129 million over the next three years toward the study. Science and Technology Deputy Minister Derek Hanekom said his department would contribute R70 million. These were the two largest funders, but several other organisations were also backing the project.

Hanekom said because South Africa had the highest infection rate, it needed to be at the forefront of research to prevent the spread of the disease.

"We have passed the stage of denial."

He said providing the gel to women did not imply they were promiscuous, but might have partners who were.

Rees said pregnant women would not be participating in the trial. This was however an area that needed research because they were at an increased risk of contracting the disease.

"Most pregnant women do not think of using a condom," she said.

The women involved in the study would be counselled and not be encouraged to be promiscuous.

The upcoming trial would also be used to see if Tenofovir provided protection against the herpes simplex virus 2 (HSV-2). During the Caprisa study researchers noted a decrease in HSV-2 transmission. - Sapa

BUSINESS LIVE

14 June, 2011 14:06

BusinessLIVE

SA, US to test new HIV gel

The Deputy Minister of Science and Technology, Derek Hanekom, and US Ambassador Donald Gips on Tuesday announced a follow-on trial to test the safety and effectiveness of 1% tenofovir gel.

South Africa is leading the charge to provide the world with the first safe and effective microbicide to protect women against HIV.

Led by Professor Helen Rees, the Director of the Wits Reproductive Health and HIV Institute (WRHI), the Follow-on African Consortium for Tenofovir Studies (FACTS) would conduct the Phase III trial to be known as FACTS 001.

"FACTS 001 follows the positive results of the CAPRISA 004 trial last year, which tested the safety and effectiveness of 1% tenofovir gel among nearly 900 women at two sites in South Africa. "The research found that using the gel before and after sex provided moderate protection against sexually transmitted HIV and Herpes Simplex Virus 2 (HSV-2). However, CAPRISA 004 was a relatively small trial (Phase IIb trial) and was not designed for licensure purposes."

FACTS 001 is a critical study being funded by the Department of Science and Technology, the Department of Health and the United States government through the US Agency for International Development (USAID). CONRAD, a leading reproductive health research organisation based in the US, is providing the gel for the study and the Technology Innovation Agency (TIA), a South African government agency focusing on supporting technological innovation, funds the technical support and monitoring carried out by the African Clinical Research Organisation (ACRO).

At a media briefing earlier on Tuesday, Hanekom said the South African government was very proud of the collaboration between the governments of South Africa and the United States of America. "We are very pleased to be associated with the FACTS 001 study and hope that the results of this study will confirm the positive CAPRISA 004 results, making it possible to provide a technology that can help protect women against HIV and Aids.

"We are very proud of the South African researchers that constantly prove that they are world-class and we would also like to honour the women that are an integral part of these studies - they are the unsung heroes." Ambassador Gips said the United States, through the President's Emergency Plan for AIDS Relief and President Obama's Global Health Initiative, was working hand-in-hand with the South African government to turn the tide of this disease.

"We are committed to empowering women and girls to protect themselves by finding new HIV prevention options. Confirming tenofovir gel's effectiveness is a fundamental and essential step in that direction," Gips added. Rees agreed that the establishment of the FACTS consortium to confirm the effectiveness of the first potential vaginal microbicide gel for women and enable licensure was extremely exciting for South African researchers. "The South African

government's support for FACTS demonstrates a new era of collaboration between researchers and government with the common vision of preventing HIV infections in women," she said.

FACTS 001 was urgently needed to provide sufficient evidence to license a new drug. The phase III study was a multi-centre, placebo-controlled, randomised trial designed to assess the safety and effectiveness of tenofovir gel used before and after sex to provide protection from sexually transmitted HIV and HSV-2 infection, Rees added. FACTS 001 planned to enrol 2,200 women aged 18 to 30 years old at seven trial sites across South Africa. This confirmatory trial was an essential step on the path to the licensing of the first potential vaginal microbicide product that would help women protect themselves from HIV and HSV-2 infection.

BEELD

Jel teen MIV bied hoop

2011-06-14 22:47

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Antoinette Pienaar

'n Reuse- kliniese proefneming met 'n vaginale jel wat antiretrovirale medisyne (ARM) bevat, kan binne 'n paar jaar lei tot die registrasie van 'n deurbraakmiddel om vroue teen MIV-besmetting te beskerm. Suid-Afrikaanse navorsers het gister by die bekendstelling van die Facts-studie in Pretoria gesê as dit suksesvol is, sal 'n geregistreerde middel die eerste metode wees waarmee vroue sonder mans se bydrae MIV-besmetting sal kan voorkom.

Navorsers van die Facts-konsortium (Follow-on African Consortium for Tenofovir Studies) wil teen Augustus 'n tenofovir-jel op 2 200 vroue begin toets. Die Mediese Navorsingsraad, die departemente van gesondheid en wetenskap en tegnologie, asook die VSA se UNAids en die organisasie Conrad is onder meer betrokke.

Dit is 'n derde fase-studie wat volg op die suksesse van verlede jaar se tweedefase Caprisa 004-studie. Prof. Helen Rees van die Universiteit van die Witwatersrand, wat die Facts-studie lei, het gister gesê Caprisa 004 het getoon die jel is 39% doeltreffend. Gereelde gebruikers se risiko om met MIV besmet te raak, was 54% minder en ongereelde gebruikers s'n 26% minder. Die Caprisa 004-studie was egter te klein om die registrasie van die middel te motiveer. Die regering het die Facts-konsortium saamgestel om 'n omvattender studie te begin. Volgens Rees het Caprisa 004 boonop getoon dit verminder herpesinfeksie met 51%. Navorsers is ernstig oor die ontwikkeling van jels soos dié omdat baie vroue nie by mans kan aandring op kondoomgebruik nie. Die jel kan tot 12 uur voordat 'n vrou ver wag om seks te hê, vaginaal toegedien word of onmiddellik daarna. Die deelnemers sal MIV-negatiewe seksueel aktiewe vroue tussen 18 en 30 wees. Hulle sal by persele in Johannesburg (Yeoville en Soweto), Durban, Kaapstad, Rustenburg en Pretoria (Soshanguve) gewerf word. Die helfte sal die jel kry en die res 'n skynmiddel. Ná 24 maande sal die navorsers kyk hoeveel vroue in elke groep met MIV besmet geraak het. Die resultate behoort in 2013 beskikbaar te wees. Volgens Rees het vorige studies getoon vroue baat by sulke navorsing deurdat hul blote

deelname lei tot veiliger seks danksy die intensiewe berading. Mnr. Derek Hanekom, adjunkminister van wetenskap en tegnologie, het gesê as die studie die middel se doeltreffendheid bevestig, kan 'n ooreenkoms tussen die staat en private sektor help dat die middel plaaslik vervaardig word en bekostigbaar is.

Die VSA sal die studie met sowat R120 miljoen finansier.

NEWS 24

AIDS FOCUS

Factfile: Breakthrough anti-HIV gel

2010-07-21 08:17

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Anti-Aids gel has unexpected spin-off

Efforts to cut the risk of women contracting HIV could have an interesting side effect - sexual pleasure.

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Vienna - Test results from an anti-HIV vaginal gel, unveiled at the International Aids Conference in Vienna, have sparked the biggest excitement in years in the war on Aids:

What is it?

A microbicide cream inserted in the vagina which aims to shield a woman against HIV in semen. Volunteers in South Africa who used the formula over 30 months had a 39% lower risk overall of HIV infection compared with counterparts who used a dummy lookalike gel.

Why all the fuss?

After two decades' effort, this is the first proof that a microbicide can offer significant protection against the human immunodeficiency virus (HIV). Some veterans compare the news to the advent in 1996 of the anti-HIV drug "cocktail" and the 2006 discovery that circumcision more than halves the infection risk for men.

Why would it help?

A microbicide would join condoms and circumcision in the arsenal for preventing the spread of HIV. Each year, some 2.7m people become infected with HIV. Treatment, a lifelong affair in the absence of a cure, is now a huge and possibly unsustainable financial burden. Microbicides would especially help women in sub-Saharan Africa, exposed to coercive sex with an infected partner who refuses to wear a condom.

Is the microbicide available?

No. The results are only for a second stage in a long, three-phase process in which new drugs are vetted for safety and efficacy. Third phases typically take two or three years. Health watchdogs then pore over the data before deciding whether to licence a product. The gel, if approved, could cost around 20 US cents per application, according to some estimates.

What is in the gel?

It contains a one-percent concentration of tenofovir, a frontline drug in the combination therapy to treat people already infected with HIV. Antiretrovirals work by preventing HIV from reproducing in CD4 immune cells. Previously tested gels, which have not used antiretrovirals, have had negligible protection or even boosted the risk of infection.

Is the gel a good enough shield?

Protection of 39% may not be high enough for watchdogs in rich countries, where 80% is a likelier benchmark. But, coupled to other prevention measures, it could be acceptable in countries in sub-Sahara Africa where two-thirds of infections occur. In South Africa alone, a gel with such effectiveness would save 1.3m new infections and avert 800 000 deaths over 20 years, the researchers say.

Who tested the gel?

The Centre for the Aids Programme of Research in South Africa, or CAPRISA. The trial, called CAPRISA 004, was tested among 889 sexually active, HIV-uninfected women living in urban and rural settings. The investigation was framed by tough ethical guidelines, in which the women were regularly advised on the risks, counselled on safe sex and given access to condoms.

What happened in the trial?

Half the volunteers were given the gel and the other the placebo. They were told to use the product within 12 hours before sex, and as soon as possible afterwards, but also within 12 hours. Each month, they were monitored for HIV infection, quizzed about their sexual activity and given more counselling. Women who became infected or pregnant were withdrawn from the trial. In the placebo group, 60 became infected, while the tally in the gel group was 38.

What about side effects?

The gel was found to be safe, which historically has been a big worry in microbicide research. Also, there was no sign

that a woman who became infected after using the gel was resistant to tenofovir. This too is a relief, given concerns that on-again, off-again use could help HIV become immune to this important drug.

Why are experts cautious?

While hailing the Phase IIb results, specialists are awaiting the outcome of the third phase before popping the champagne. Among the questions is how the gel was used. Women who used it most consistently had a protection of 54%; those who used it least consistently, just 28%. Effectiveness fell markedly over the course of trial, possibly because use of the microbicide declined among some women.

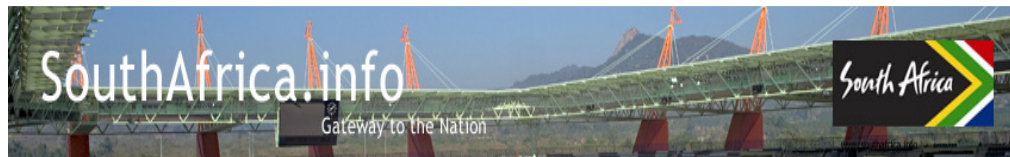
What about the future?

If the CAPRISA 004 data are confirmed, this could be just the start of an extraordinary tale for microbicides. Scientists will want to see whether different antiretrovirals or ways of using the gel - perhaps through a slow-release vaginal ring - could boost protection. Many are inspired by the slow start but ultimately glittering success of HIV drugs, now a lifeline for 5.2m people. Another avenue of exploration is whether the microbicide is effective in anal intercourse, where the statistical risk of infection is 10 times higher than in vaginal sex.

Sources: CAPRISA IIb data, published in US journal science; CAPRISA researchers; interviews and conferences with non-CAPRISA specialists at 18th International Aids Conference.

- AFP

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Fri, 17 Jun 2011



Health care

SA's anti-HIV gel trial enters next phase

Gabi Khumalo

|

15 June 2011

After encouraging results on a pioneering vaginal gel which reduces the risk of HIV and genital herpes infection, South Africa, in partnership with the United States, has launched a follow-up study to test the safety of the gel. The Phase III trial, to be known as FACTS 001, will be conducted by the Follow-on African Consortium for Tenofovir Studies (FACTS) led by Professor Helen Rees, director of the Wits Reproductive Health and HIV Institute (WRHI). It is expected to start by the end of July and run for 24 months.

Previous trial



Professor Salim Abdool Karim, director of the Centre for the Aids Programme of Research in South Africa (Caprisa), at work in one of the centre's laboratories (Photo:)

The study prior to this, known as CAPRISA 004, was conducted last year by the Centre for the Aids Programme of Research in South Africa (Caprisa) on nearly 900 women in KwaZulu-Natal. It showed that the use of the gel containing the antiretroviral drug tenofovir reduced HIV infection by 39 percent and also reduces the risk of contracting genital herpes by 51 percent. However, CAPRISA 004 was a relatively small trial (Phase IIb trial) and was not designed for licensure purposes. On Tuesday, South Africa's Department of Science and Technology, in partnership with the United States, launched FACTS 001, which will test the safety and effectiveness of 1 percent tenofovir gel.

FACTS 001 will be a bigger study than CAPRISA 004, involving 2 200 women aged 18 to 30 years at seven trial sites across South Africa.

Giving power to women

Speaking at the launch of FACTS 001, Deputy Science and Technology Minister Derek Hanekom said the government was looking forward to this stage of the trial, and was very proud of the collaboration between the South African government and United States. He noted that while people should continue to condomise and be faithful, and while research for vaccines should continue, once the results regarding the gel were positive and confirmed, it would be possible to help protect women against HIV/Aids. "This product does

something different: it gives women the power to negotiate and make decisions for themselves," Hanekom said. "It needs to be done. We are ready, and if it confirms its effectiveness, we will soon put it on the market, combined with the roll-out of the treatment."

Professor Rees said the research so far had found that using the gel before and after sex provided moderate protection against HIV and Herpes Simplex. "The establishment of the FACTS consortium to confirm the effectiveness of the first vaginal microbicide gel for women and enable licensure is extremely exciting for South African researchers," Rees said. "The objectives of the FACTS 001 confirm the CAPRISA 004 results in larger more diverse populations. "The South African government's support for FACTS demonstrates a new era of collaboration between researchers and government with the common vision of preventing HIV infections in women." The government had funded the trial with an amount of R17-million for a three-year period. United States Ambassador Donald Gips commended the South African government for its decision to fund the FACTS study and partnering with the US, which has pledged to fund the study for R129-million for a three-year period. "The study offers a new tool to prevent HIV/Aids," Gips said. "We have to figure out how to prevent more people from being infected with the disease. It is very urgent for the researchers to complete the trial for its approval, because protecting women and girls from contracting the disease is very crucial.

"We are committed to empowering women and girls to protect themselves by finding new HIV prevention options," Gips said. "Confirming tenofovir gel's effectiveness is a fundamental and essential step in the right direction. Together, government and civil society are making strides to slow down the infection, and the US is very proud to support you."

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Fast-track anti-HIV gel, says minister

FARANAAZ PARKER VIENNA, AUSTRIA - Jul 23 2010 11:41

ARTICLE TOOLS



The South African government would consider fast-tracking a groundbreaking HIV-blocking vaginal gel through regulatory processes to get it into clinics faster, Health Minister Aaron Motsoaledi told the International Aids Council in Vienna this week.

"Anything that has to do with combating HIV/Aids must be given preference in terms of the regulatory functions," Motsoaledi told delegates at the conference, where the results of the South African trial of the gel were released this week.

Tenofovir gel, developed by researchers at the Centre for the Aids Programme of Research in South Africa (Caprisa) in Durban, was found to be 39% effective in reducing the risk of HIV infection in women.

The gel has also been shown to have a 51% protective effect against genital herpes. Because genital herpes sufferers are more likely to acquire or transmit HIV, preventing such infections could also help prevent HIV infection in the long term.

The trial proved for the first time that a topically applied substance or microbicide can prevent HIV transmission.

Researchers believe that the gel, hailed as revolutionary, could prevent up to 1.3-million new infections and avert 800 000 deaths in South Africa in the next 20 years. Biological factors make women more likely to acquire HIV during unprotected sex and they carry a disproportionate burden of the disease. About 60% of new infections are among women and girls.

Plans in motion

According to Henry Gabelnick, executive director of Conrad, the US-based agency that supplied the gel, moves are already under way to smooth its path from concept to clinic. Gabelnick said that the

science and technology department's technology innovation agency will form a public-private partnership with a South African-based pharmaceutical company to set up manufacturing capabilities and win regulatory approval from the Medicines Control Council (MCC).

Interested parties had "been working on this for a year now", he said. However, the gel would first have to prove itself in a larger trial.

Salim Abdool Karim, one of the principal investigators in the trial, said a multi-stakeholder meeting has already been planned to chart the way forward for that trial. The meeting, to take place later this year, will be jointly hosted by the South African government and the World Health Organisation and will bring together researchers, policymakers and ethicists. "The highest priority is for us to develop a consensus about the next step," said Abdool Karim.

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He said the group would try to establish the level of evidence required by regulatory bodies such as the MCC to license the gel as a medicine. Researchers will design the follow-up confirmatory study so that licensing can take place more speedily.

"Those confirming studies need to be in the field six months from now and they should be designed to provide the information that the regulator wants in order to license this product," he said.

Because the study needs independent confirmation, a different research group will conduct those trials.

The science and technology department, in consultation with leaders in the sector, last year selected Helen Rees, executive director of the reproductive health and HIV unit at Wits University, and Glenda Gray, co-director of the perinatal HIV research unit, to lead the new initiative. They have brought on board researchers from the top 10 HIV research units in the country.

Further research

As well as scaling up the number of women involved in the study, further research would address issues such as whether a long-acting formulation, a vaginal ring mechanism or an alternative dosage will produce better results.

A long-acting gel, for instance, would allow women to dose themselves only once a day and could result in better adherence. The gel used in the trial had to be applied at least 12 hours before sex and again no more than 12 hours afterwards.

If the gel is approved for public use, it will need better marketing to make it more attractive to consumers. It currently comprises a clear white plastic applicator similar to a tampon applicator, while the gel itself is clear, odourless and tasteless. The packaging is clear and white.

Abdool Karim said it would be up to marketers to figure out how to "make the gel sexy and

desirable".

He plans to return to the laboratory to understand why some women still become infected while on tenofovir. This work will be carried out at a new high-tech laboratory under construction at the University of KwaZulu-Natal's Doris Duke Medical Research Institute.

He is contemplating a more ambitious study, which will attempt to understand the impact of a product such as tenofovir gel on an entire community, including women's partners and babies. Such a trial could involve more than 4 000 people in 12 communities and will be carried out over five years.
