

Press statement

Cellulose sulfate microbicide trial stopped

Statement developed by the World Health Organization and UNAIDS

Geneva, 31 January 2007 – A Phase III study of the candidate microbicide* cellulose sulfate to prevent HIV transmission in women has been stopped prematurely because of a higher number of HIV infections in the active compared with the placebo group. The study was sponsored by CONRAD and conducted in Benin, India, South Africa and Uganda. A second study on the same product sponsored by Family Health International conducted in Nigeria has also been stopped because of the safety concerns in the first trial. This is a disappointing and unexpected setback in the search for a safe and effective microbicide that can be used by women to protect themselves against HIV infection. Cellulose sulfate was one of four compounds being evaluated in large-scale studies of effectiveness among women at high risk of HIV infection.

Currently there are three other Phase III microbicide studies under way. The Carraguard study (sponsored by the Population Council and conducted in three sites in South Africa) is nearing completion and results are expected by the end of 2007. Another product, PRO 2000, is being tested in one study in five sites in South Africa, Tanzania and Uganda (results expected in 2009) as well as in a second study in seven sites in Malawi, South Africa, Zambia and Zimbabwe (results expected in 2008). In this second study a further compound, BufferGel, (a vaginal defence enhancer) is being tested. All the other compounds mentioned are products that block HIV infection – known as HIV entry inhibitors – and have a similar presumed mechanism of action.

Data from these clinical trials will be indispensable to the researchers and developers of emerging and future microbicide candidates. It is important for the microbicide field to understand why cellulose sulfate was associated with a higher risk of HIV infection than the placebo product. At present there is no explanation for this higher rate of transmission of HIV. The need to continue research to find a user-controlled means of preventing HIV infection in women is urgent. Despite the effectiveness and availability of condoms, the HIV epidemic continues to spread and the search for a safe and effective microbicide is a vital part of the effort to stem the spread of the HIV epidemic.

**Microbicides are products being developed to be used by women to reduce the transmission of HIV during sexual intercourse. A microbicide could take the form of a gel, cream, film, tablet or sponge, or be contained in a vaginal ring that releases the active ingredient gradually.*

For further information on the trials see www.conrad.org and www.fhi.org. For more information about microbicide research, go to the web site of the Alliance for Microbicide Development (www.microbicide.org)

Contact

Christopher Powell | WHO Geneva | + 41 22 791 2888 / mobile +41 79 217 3425 | powellc@who.int

Sophie Barton-Knott | UNAIDS Geneva | +41 22 791 1967 | bartonknotts@unaids.org