

MDP Statement on CONRAD cellulose sulphate trial closure

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CONRAD and FHI today announced their decision to halt clinical trials of cellulose sulphate to ensure the safety of the trial participants. The trials were stopped following an interim data analysis based on the information presented to the Independent Data Monitoring Committee. This data analysis indicated that use of cellulose sulphate could lead to an increased risk of HIV infection. MDP is studying a different, chemically unrelated compound called PRO2000. Studies of PRO2000 in the test tube and in animals concluded that PRO2000 was safe and would be well-tolerated.

The MDP trial has now recruited over 3000 participants. The MDP Independent Data Monitoring Committee (IDMC) reviewed the trial data on 10 January 2007 and reported that the trial should continue according to the protocol. In the light of the results from the cellulose sulphate trials, the IDMC intends to meet again in the near future to review the most recent data from the MDP301 trial, as ensuring the safety of the women in the trial is of paramount importance.

For these reasons, the MDP believes it is both safe and important to continue the MDP301 trial. Jonathan Weber, MDP investigator at Imperial College said 'Although it is disappointing that the cellulose sulphate trial has closed, this is just one of four products currently being investigated worldwide. Women still need a safe, effective microbicide to protect themselves from HIV'. The MDP trial sites in South Africa, Uganda, Zambia and Tanzania will notify local communities of this development.