

# **PC37 Informed consent and participant understanding of trial procedures in a Phase III Pilot study**

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## **ABSTRACT TEXT**

### **Background:**

MDP301 is a large multi-centre Phase III microbicides trial, recruiting nearly 10,000 female participants from sites in South Africa, Zambia, Tanzania and Uganda. Trial participants come from a wide range of socio-economic and educational backgrounds, and ensuring understanding of trial concepts and procedures is a challenge. Assessing potential participants' comprehension prior to enrolment has become an important part of the consent process.

### **Methods:**

Prior to the Phase III trial, a four-week pilot study involving 297 women was conducted using placebo gel. In depth interviews were carried out at the end of the study and open questions used to assess women's knowledge and understanding of key issues, including: gel was a placebo and did not protect against HIV, other STIs or pregnancy; condoms protect against HIV; and participation would involve answering sensitive questions about sexual behaviour. The data were analysed using NVivo.

### **Results:**

Key messages were understood and retained with varying degrees of success. The message that condoms protect against HIV was well understood (289/297). However, other information appeared to have been less well absorbed. Preliminary analysis of a subset of 56 interviews indicated that 21% of women believed the placebo gel offered protection against HIV, other STIs or pregnancy. 29% said they had not expected an HIV test or sensitive questions as part of participation in the study. It was common for women to have a partial grasp of the information that had been given, and such women's accounts displayed confusion, contradiction and uncertainty.

### **Conclusion:**

The majority of participants had a good understanding of information given during the informed consent process at the time. However, after four weeks, a sizeable proportion (29%) had only a partial understanding of the key trial issues. In order to assess understanding in the Phase III trial, which involves 12 and 24 months of follow up, a comprehension tool has been developed to assess the level of understanding of key messages. This tool will be used at enrolment to ensure that consent is truly 'informed', and may be used throughout the follow up period to assess continued understanding and to trigger further directed information giving.

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