

Randomised Controlled Trial of 6% Cellulose Sulfate (CF) Gel and the Effect on Vaginal Human Immunodeficiency Virus (HIV) Transmission

Submission date 03/06/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 08/07/2005	Overall study status Completed	☐ Protocol
Last Edited 09/03/2011	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Lut Van Damme

Contact details

1611 N Kent Street
Suite 806
Arlington, VA
United States of America
22209
+1 703 276 4020
lvandamme@conrad.org

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00153777

Protocol serial number

C03-090

Study information

Scientific Title

Study objectives

Effect on vaginal male-to-female transmission of HIV/Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT). Null hypotheses (of no effect) are tested.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

HIV infection

Interventions

Randomized to 6% CS gel or Placebo gel; both arms receive condoms and safer sex counseling. Any curable sexually transmitted infection (STI) or urinary tract infection (UTI) will be treated. Referrals for other conditions. Three monthly gynecological exam with STI testing.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Cellulose sulfate

Primary outcome(s)

HIV infection (incident)

Key secondary outcome(s)

NG infection; CT infection

Completion date

31/01/2007

Eligibility

Key inclusion criteria

Healthy women at risk of HIV infection through their own sexual behavior.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

HIV positive women or at risk of HIV through other transmission routes; pregnant women.

Date of first enrolment

13/06/2005

Date of final enrolment

31/01/2007

Locations

Countries of recruitment

Benin

Burkina Faso

India

South Africa

Uganda

United States of America

Study participating centre

1611 N Kent Street

Arlington, VA

United States of America

22209

Sponsor information

Organisation

CONRAD (USA)

Funder(s)

Funder type

Government

Funder Name

US Agency for International Development (USAID): \$12M

Funder Name

Bill and Melinda Gates Foundation (USA): \$12M

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/07/2008		Yes	No
Results article	results	27/10/2010		Yes	No