ISRCTN95638385 https://doi.org/10.1186/ISRCTN95638385

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00153777

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
International

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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 measure
HIV infection (incident)

Secondary outcome measures
NG infection; CT infection

Overall study start date
13/06/2005

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

Age group
Adult

Sex
Female

Target number of participants
2574

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
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Sponsor information

Organisation
CONRAD (USA)

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Sponsor type
Government

Website
http://www.conrad.org

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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