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Expanded safety and acceptability study of 6% cellulose sulphate

Submission date	Recruitment status	[_] Prospectively registered
19/03/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/04/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2022	Urological and Genital Diseases	

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

Secondary identifying numbers
WHO/HRP ID: A15006

Study information

Scientific Title
Expanded safety and acceptability study of 6% cellulose sulphate

Study objectives
Local tolerance and acceptability of cellulose sulphate (CS) gel applied vaginally twice daily for seven days.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was approved by scientific and ethics review committees at each implementing centre and the World Health Organization.

Study design
A phase I randomised, closed label, comparative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sexually transmitted infection (STI) prevention

Interventions
1. Test groups using Cellulose Sulphate (CS) gel with or without concurrent intercourse
2. Control groups using K-Y jelly with or without concurrent intercourse

Total duration of involvement in the study, including screening, admission, completion and follow up, is approximately one month per subject.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)

Cellulose sulphate (CS) gel

Primary outcome measure
The number of women who experienced any signs and/or symptoms of genital irritation as reported by volunteers at any time during follow-up or as determined by naked eye examination of the genitalia, on colposcopy or microbiologic tests.

Secondary outcome measures
Adverse events

Overall study start date
01/12/2001

Completion date
01/07/2003

Eligibility

Key inclusion criteria
1. Healthy, sexually abstinent and sexually active women
2. Considered to be at low risk for human immunodeficiency virus (HIV)
3. Recruited from family planning clinics and local communities in Kampala (Uganda), Mumbai (India), and Sagamu (Nigeria)
4. Aged between 18 and 50 years
5. Had regular menstrual cycles, or were on injectable contraceptives and amenorrhoeic for at least 6 months
6. Were not at risk for pregnancy (because of tubal ligation, steroidal contraceptives, or abstinence)
7. Willing to adhere to the study protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
180

Total final enrolment
180

Key exclusion criteria

1. Known to have an allergy to any component of CS gel or K-Y Jelly or condoms (cohort II only)
2. Currently pregnant or within 2 months from last pregnancy outcome
3. Known to abuse drug or alcohol
4. Had evidence of an infection with Trichomonas vaginalis, Candidiasis or bacterial vaginosis which did not resolve with treatment or if they had gonorrhoea or a chlamydial infection
5. Had a history of herpes or condylomata within the past 6 months
6. Had non-iatrogenic abnormal colposcopy findings involving deep disruption of the genital epithelium at enrolment

Date of first enrolment
01/12/2001

Date of final enrolment
01/07/2003

Locations

Countries of recruitment
India

Nigeria

Switzerland

Uganda

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
UNDP/UNFPA/WHO/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction

Sponsor details
World Health Organization
20, Avenue Appia
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CH-1211

Sponsor type
Research organisation

Website
http://www.who.int/reproductive-health/hrp/

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA) /World Health Organization (WHO)/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		02/12/2005		Yes	No