

Expanded safety and acceptability study of 6% cellulose sulphate

Submission date
19/03/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
01/04/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
10/11/2022

Condition category
Urological and Genital Diseases

☐ Individual participant data

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

Geneva-27

Switzerland

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 |