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A phase I/II study on the safety, tolerance and acceptability of a vaginal gel containing sodium lauryl sulphate (invisible condom) in healthy subjects

Submission date
18/11/2005

Recruitment status
No longer recruiting

Registration date
18/11/2005

Overall study status
Completed

Last Edited
16/11/2009

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
MCT-67531

Study information

Scientific Title

Study objectives
To evaluate the safety, tolerance and acceptability of a vaginal gel formulation containing sodium lauryl sulphate (SLS) (invisible condom) in healthy women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee, CHUQ, Quebec, QC approved on the 18th November 2003
2. Cameroon National Ethics Committee approved on the 19th January 2005

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prevention of sexual transmitted infections (STIs) including human immunodeficiency virus (HIV)

Interventions
Trial groups:
Group 1: Gel alone
Group 2: Gel plus SLS
Group 3: Placebo
The study will be divided in two parts. Part A is a short-term study using escalating gel applications (1 x, 2 x and 3 x) daily for 2 weeks. In Part B, they will receive the gel twice daily for 2 months.

Trial details received 12 Sept 2005

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sodium lauryl sulphate

Primary outcome(s)
1. Safety and tolerance measured at all visits by gynecological and colposcopic examinations
2. Nugent score
3. Clinical laboratory safety tests

Key secondary outcome(s)
Acceptability measured at the end of gel application period by acceptability questionnaire

Completion date
31/01/2007

Eligibility

Key inclusion criteria
1. Signed an informed consent
2. Healthy female subjects aged between 18 to 49 years
3. Normal physical and gynaecological examinations
4. Normal colposcopic examination
5. Have regular menstrual cycle with 21 - 40 days between menses
6. Human immunodeficiency virus (HIV)-negative subjects and at low risk of acquiring HIV
7. At low risk of getting sexually transmitted diseases (STDs), i.e., sexually abstinent or having history of protected sexual intercourse or having a stable sexual partner
8 Agreeing to abstain from sexual intercourse from screening to the end of the study (for sexually abstinent subjects)
9. Agreeing to have a minimum of four sexual intercourses for each period of 2 weeks of gel application (for sexually active subjects)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Clinically significant abnormal physical and/or gynaecological examination
2. Clinically significant abnormal laboratory findings
3. Allergy to applicator material (polyethylene) or to gel polymer (polyoxyethylene - polyoxypropylene) or to latex
4. Participation in any investigational study involving drugs, vaccines or microbicides in the last 30 days or participation in a study involving the invisible condom
5. History of toxic shock syndrome
6. HIV infection
7. Bacterial vaginosis or Candida or Trichomonas at time of screening
8. STDs (gonorrheae, chlamydia, syphilis, genital herpes, chancroid) at time of screening
9. Breakthrough menstrual bleeding, or vaginal bleeding during or following sexual intercourse, in the last 3 months

10. Intravenous (IV) drug use except for medical reasons in the last year
11. Pregnant at enrolment or breast-feeding
12. Having received antibiotics in the last 14 days
13. Subjects considered as unreliable or unable to understand or follow the study protocol directions
14. Use of an intrauterine device

Date of first enrolment
01/01/2005

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
Cameroon

Canada

Study participating centre
Centre de Rech. en Inf. de L'Univ. Laval
Sainte-Foy
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Sponsor information

Organisation
Laval University (Canada)

ROR
https://ror.org/04sjchr03

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-67531)

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	01/11/2009		Yes	No