

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

<b>Submission date</b> 18/11/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/11/2009	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

**Secondary outcome measures**

Acceptability measured at the end of gel application period by acceptability questionnaire

**Overall study start date**

01/01/2005

**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 intercours for each period of 2 weeks of gel application (for sexually active subjects)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

## Target number of participants

452

## 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 (gonorrhoeae, 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

Canada

G1V 4G2

## Sponsor information

### Organisation

Laval University (Canada)

### **Sponsor details**

Cité Universitaire  
C.P. 2208  
Québec  
Canada  
G1K 7P4

### **Sponsor type**

University/education

### **Website**

<http://www2.ulaval.ca/>

### **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**

### **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?
<a href="#">Results article</a>	results	01/11/2009		Yes	No