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MIA-002: A randomised, vaginal microbicide trial assessing the safety of PRO 2000/5 gel (P) versus vehicle placebo in Uganda

Submission date
11/08/2005

Registration date
15/09/2005

Last Edited
25/05/2010

Recruitment status
No longer recruiting

Overall study status
Completed

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MIA-002 Version 3

Study information

Scientific Title

Acronym
MIA: Microbicides Initiative in Africa

Study objectives
That PRO 2000/5 (P) gel in 0.5% and 2% formulations are as safe and acceptable for women to use as a vehicle placebo gel

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
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
HIV-1

Interventions
Two active study products (0.5% and 2% PRO 2000/5 Gel [P]) and a matched vehicle placebo (Placebo Gel [P]) inserted intra-vaginally twice a day for 28 days

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
PRO 2000/5 gel

Primary outcome measure
The primary end-points are local and systemic safety parameters, namely:
1. Deep (any size) or extensive superficial (greater than or equal to 4 times the size of the tip of a 5 x 10 mm cotton-tipped swab) genital epithelial disruption visible on naked eye examination or colposcopy
2. The appearance of a coagulation abnormality which is considered clinically relevant by the local investigator/Trial Management Group

Secondary outcome measures
The secondary end-points are:
1. Grade 3 clinical or laboratory adverse event confirmed on examination or repeat testing respectively, thought to be possibly or probably related to gel
2. Grade 3 unexpected vaginal bleeding as reported at interview or on a diary card or recorded on examination
3. Grade 1 unexpected vaginal bleeding not due to menses
4. Acceptability of gel as assessed by a semi-structured questionnaire
5. Alterations in vaginal flora assessed by Nugent score performed on Gram-stained slides

Overall study start date
11/06/2003

Completion date
17/11/2004

Eligibility

Key inclusion criteria
1. Healthy* women aged between 18 and 45
2. Sexually active and likely to remain so for the duration of the study at a minimum rate of twice per week
3. Willing to undergo a genital infection screen
4. Willing to undergo a human immunodeficiency virus (HIV) test**
5. Willing to accept health education about condoms and to be supplied with condoms to be used at every episode of sexual intercourse during the study, and has used condoms before
6. Able to give informed consent
7. Either HIV negative or HIV positive in a monogamous sexual relationship with another person who is also HIV positive and who will give his signed consent to say he has been informed and understands about the trial

* HIV-seropositive women will be eligible providing they fulfil all other criteria including exclusion 10, and have a primary partner who is also HIV-seropositive. Antiretroviral therapy is permitted provided it has been stable for 2 months prior to enrolment and is not expected to change during participation in the study
** Unnecessary if HIV-positivity documented in medical records at Nsambya Hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
180

Key exclusion criteria
1. Pregnant, wanting to become pregnant or within 6 weeks postpartum
2. Current genital tract epithelial ulceration/disruption
3. Untreated gonococcal, chlamydial, or trichomonal infection, syphilis or symptomatic bacterial vaginosis
4. Is HIV positive and in a sexual relationship with someone who is not HIV infected, who will not have an HIV test before the trial, and/or who will not sign a consent form for the trial
5. Abnormal (grade II) haematology, biochemistry
6. Cervical intraepithelial neoplasia (CIN) greater than or equal to CIN II within 3 months
7. Acute/subacute pelvic inflammatory disease
8. Clinical coagulation disorder
9. Latex allergy
10. Current, recent (within 2 weeks) or on-going ill health that necessitates drug treatment (other than prophylaxis) or attendance at hospital***
11. Post-coital or intermenstrual bleeding in the past 3 months
12. (If post-natal) Persistent abnormal vaginal discharge
13. No reported use of condoms between screening and enrolment
14. Having participated in another microbicide trial in previous 30 days
15. Considered unlikely to be able to comply with protocol

*** Except for HIV positive women from the HIV clinic, where the same exclusion applies without the phrase 'or ongoing'; women may enter the study following the initiation of appropriate treatment

Date of first enrolment
11/06/2003

Date of final enrolment
17/11/2004

Locations

Countries of recruitment
England

Uganda

United Kingdom

Study participating centre
222 Euston Road
London
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NW1 2DA

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
St Mary's Campus
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Winston Churchill Wing
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W2 1NY

Sponsor type
University/education

Website
http://www.imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
The project was funded by the European Commission

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	01/06/2010		Yes	No