ISRCTN64716212 https://doi.org/10.1186/ISRCTN64716212

An international multi-centre, randomised, double-blind, placebo controlled trial to evaluate the efficacy and safety of 0.5% and 2% Pro 2000/5 gels for the prevention of vaginally acquired human immunodeficiency virus (HIV) infections

Submission date
03/05/2005

Recruitment status
No longer recruiting

Registration date
06/07/2005

Overall study status
Completed

Last Edited
14/03/2017

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.mdp.mrc.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Sheena McCormack

Contact details
MRC Clinical Trials Unit
222 Euston Rd
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00262106

Secondary identifying numbers
MDP301

Study information

Scientific Title
An international multi-centre, randomised, double-blind, placebo controlled trial to evaluate the efficacy and safety of 0.5% and 2% Pro 2000/5 gels for the prevention of vaginally acquired human immunodeficiency virus (HIV) infections

Acronym
MDP301

Study objectives
Null Hypothesis: That there is no difference in aquisition of HIV and sexually transmitted infections (STIs) in women using Pro2000 and placebo gel.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
International multi-centre randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Pro 2000/5 (P) 0.5% and 2% gels, Placebo gel

Intervention Type
Drug

Phase
Not Applicable

Primary outcome measure
1. Acquisition of HIV infection before or at the 9 month time point, confirmed by a Central Reference Laboratory, in participants confirmed to be HIV negative at enrolment
2. Grade 3 (severe) or 4 (life-threatening) clinical events noted through systematically solicited questions, or laboratory adverse events confirmed on examination or repeat testing respectively

Secondary outcome measures
1. Acquisition of HIV infection before or at the 6 and 12 month time points, confirmed by a Central Reference Laboratory, in participants confirmed to be HIV negative at enrolment
2. Acquisition of herpes simplex virus type 2 (HSV-2) in women uninfected at enrolment
3. The point prevalence of Neisseria gonorrhoeae (NG) or Chlamydia trachomatis (CT) after 24 weeks of follow-up, determined by a positive nucleic acid amplification assay
4. All systematically solicited genital adverse events
5. All clinical and laboratory adverse events

Overall study start date
01/08/2005

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Sexually active
2. HIV-negative healthy women
3. Not pregnant

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
9,673

Key exclusion criteria

1. Unable or unwilling to provide a reliable method of contact for the field team
2. Likely to move permanently out of the area within the next year
3. Likely to have sex more than 14 times a week on a regular basis during the course of follow-up
4. Using spermicides regularly
5. Pregnant or within 6 weeks postpartum at enrolment
6. Has grade 3 clinical or laboratory abnormalities which are considered by the clinician or the Trial Management Group to make enrolment inadvisable
7. Requiring referral for assessment of a clinically suspicious cervical lesion
8. Treatment to the cervix, or to the womb through the cervix, within 30 days of enrolment
9. Known latex allergy
10. Participating, or having participated within 30 days of enrolment, in a clinical trial of an unlicensed product, microbicide, barrier method or any other intervention likely to impact on the outcome of this trial
11. Considered unlikely to be able to comply with the protocol

Date of first enrolment
01/08/2005

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
England

South Africa

Tanzania

Uganda

United Kingdom

Zambia

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
Ian Viney
MRC Centre London
Stephenson House
158-160 North Gower Street
London
United Kingdom
NW1 2DA

Sponsor type
Research council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Government

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	09/10/2009		Yes	No
Protocol article	protocol	27/10/2009		Yes	No
Results article	informed consent results	13/06/2010		Yes	No
Results article	vaginal gel results	16/10/2010		Yes	No
Results article	participant response results	21/01/2011		Yes	No
Results article	substudy HIV-1 testing algorithm results	01/01/2012		Yes	No
Other publications	effects of injectable hormonal contraceptives	28/01/2012		Yes	No
Results article	results	01/02/2013		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	results	01/05/2015		Yes	No
Results article	results	01/01/2016		Yes	No
Results article	results	01/01/2016		Yes	No
Results article	HSV-2 results	12/12/2016		Yes	No
Results article	results	11/03/2017		Yes	No