ISRCTN88319802 https://doi.org/10.1186/ISRCTN88319802

Magnetic Resonance Imaging (MRI) scan of the vagina to measure how well the microbicide 0.5% PRO 2000/5 Gel (P) spreads around and remains within the vagina

Submission date
22/07/2009

Registration date
07/09/2009

Last Edited
16/05/2014

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=17

Study website
http://www.yorkhivresearch.org.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 3

Study information

Scientific Title
Magnetic resonance imaging study of the genital tract distribution and retention of microbicide 0.5% PRO 2000/5 Gel (P) in vivo: a partially blinded, randomised, two-arm, single-centre study

Acronym
MDP102/York 1:MRI

Study objectives
To assess and compare the distribution and retention of 0.5% PRO 2000/5 Gel (P), firstly over a 6-hour period and then before and after sexual intercourse; both using condoms and without using condoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge 1 Research Ethics Committee on 30/01/2009 (ref: 08/H0304/99). The SSA (LREC York) also approved on the same date (ref: 08/H1311/115).

Study design
Partially blinded randomised two-arm single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at http://www.yorkhivresearch.org.uk/

Health condition(s) or problem(s) studied
Sexually transmitted infection, human immunodeficiency virus (HIV) prevention

Interventions

All female participants will receive an intravaginal dose of 0.5% PRO 2000/5 Gel (P) mixed with gadolinium (Gd-PRO 2000/5 Gel [P]) and an MRI assessment at visit 2 (scans pre-application, immediate post-application, post-application plus two hours, post-application plus six hours), and at visits 3 and 4. At visit 3 participants are randomised 1:1 to differing arms:
Arm 1: participant will use a condom at visit 3, and then will not use a condom at visit 4
Arm 2: participant will not use a condom at visit 3, and use a condom at visit 4

MRI assessments for these two conditions at each of the visits will be conducted at two time-points:
1. Immediately post-application and pre-coitus
2. Post-coitus

Updated 16/05/2014: the trial was stopped on 31/03/2010.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
PRO 2000/5 Gel (P), gadolinium

Primary outcome measure
Quantification of the amount of gel (signal intensity) at predetermined sites within the genital tract (lower vagina, mid vagina, cervix, posterior fornix, lateral fornix), at differing times after gel insertion, both pre and post-coitus.

Secondary outcome measures
1. Assessment of the length of cervico-vaginal mucosa covered by gel
2. Visual assessment of the uniformity and distribution of gel within the genital tract

Overall study start date
01/10/2009

Completion date
31/03/2010

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Female participants:
1. Aged 18 - 45 years. The upper age of 45 is felt to be important due to the need for female participants to have a regular menstrual cycle.
2. Sexually active with a current, stable, regular male partner
3. Not currently using condoms with this partner. This is important so that it is acceptable to randomise a participant to not using condoms.

4. Using hormonal contraception (except hormone-releasing intrauterine devices [IUDs])
5. Not known to be allergic to gadolinium
6. Willing and able to adhere to the study conditions and methodology
7. Willing and able to give written and signed informed consent to trial participation and procedures
8. Willing to use condoms in the context of the trial
9. Willing to have a human immunodeficiency virus (HIV) test (venous blood, HIV antibody test)

Male partners:
1. Aged 18 - 55 years. The upper age limit for men is felt to be appropriate to minimise age related conditions.
2. Independently reports that they are not currently using condoms with this partner
3. Not known to be allergic to gadolinium (as the male partner may come into contact with gadolinium during the act of unprotected coitus for study purposes)
4. Willing and able to adhere to the study conditions and methodology
5. Willing and able to give written informed consent to trial participation and procedures
6. Willing to use condoms in the context of the trial
7. Willing to have a HIV test (venous blood, HIV antibody test)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10 healthy women and their healthy regular male partners (total = 20)

Key exclusion criteria
Females only:
1. Pregnancy or lactation
2. Gynaecological instrumentation and procedures of the cervix/uterus in the last three months including cervical polypectomy, dilatation and curettage, endometrial biopsy, loop excision, etc.
3. Contraindication to MRI such as intracerebral aneurysm clip or implanted electronic devices
4. Currently participating in, or having participated in the last 3 months prior to the first screening visit, any other vaginal microbicide or mucosal vaccine study or clinical trial of an investigational agent

Females and males:
1. Untreated syphilis, gonorrhoea, trichomonas, chlamydia, candida or bacterial vaginosis
2. Current genital tract infection
3. HIV infection
4. Active hepatitis B or C infection

5. History of coagulation disorders
6. Significant haematological, biochemical, or coagulation assay abnormalities on screening
7. Unlikely to comply with protocol

Date of first enrolment
01/10/2009

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull York Medical School (HYMS)
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Sponsor information

Organisation
University of York (UK)

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Sponsor type
University/education

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ROR

https://ror.org/04m01e293

Funder(s)

Funder type
Research organisation

Funder Name
Department for International Development (DFID) (UK)

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?
HRA research summary			28/06/2023	No	No