

# 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

<b>Submission date</b> 22/07/2009	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/09/2009	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/05/2014	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=17](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

### Contact name

Prof Charles Lacey

### Contact details

Hull York Medical School (HYMS)  
University of York  
Heslington  
York  
United Kingdom  
YO10 5DD  
+44 (0)1904 725474  
[charles.Lacey@hyms.ac.uk](mailto:charles.Lacey@hyms.ac.uk)

## 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)

York

United Kingdom

YO10 5DD

## **Sponsor information**

**Organisation**

University of York (UK)

**Sponsor details**

c/o Sue Final

Heslington

York

England

United Kingdom

YO10 5DD

+44 (0)1904 430000

smf3@york.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.york.ac.uk/>

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?
<a href="#">HRA research summary</a>			28/06/2023	No	No