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# Tolerability and completion of Maraviroc compared to Kaletra® in combination with Truvada® for HIV Post Exposure Prophylaxis

**Submission date**
22/07/2011

**Recruitment status**
No longer recruiting

**Registration date**
09/03/2012

**Overall study status**
Completed

**Last Edited**
13/02/2018

**Condition category**
Infections and Infestations

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

## Plain English summary of protocol

Background and study aims
Post-exposure prophylaxis (PEP) involves taking anti-HIV medications as soon as possible after you may have been exposed to HIV to try to reduce the chance of becoming HIV positive. It is readily available for healthcare workers following occupational HIV exposure (during the performance of their job duties). The current Department of Health guidelines recommend treatment with combination of three drugs for 28 days, which should be started as soon as possible after the exposure, ideally within one hour. Post-exposure prophylaxis following non-occupational exposure to HIV (e.g., sexual contact, sharing of injection drug needles) is increasingly being provided and many countries including the UK have now developed guidelines for its use. However, studies also suggest that PEP is often poorly tolerated, with patients frequently reporting side effects and not completing their treatment. Identifying drug combinations likely to be better tolerated would therefore be extremely useful. The aim of this study is to determine if, when used in combination with tenofovir/emtricitabine, maraviroc is superior to lopinavir/ritonavir with respect to the proportion of patients who complete 28 days of PEP without developing adverse events.

Who can participate?
Patients aged 18 or over receiving PEP following occupational or non-occupational HIV exposure.

What does the study involve?
Participants are randomly allocated to either the control group or the experimental group. The control group receive 28 days' treatment with tenofovir/emtricitabine (one tablet once daily) and lopinavir/ritonavir (two tablets twice daily). These drugs are the standard combination currently in use in most centers for PEP in the UK. The experimental group receive 28 days' treatment with tenofovir/emtricitabine (one tablet once daily) and maraviroc (one tablet twice daily). Participants attend a follow-up visit 3 months after the last dose of medication.

What are the possible benefits and risks of participating?
Collecting blood samples could cause discomfort and may leave temporary bruises. Every effort will be made to minimise this. No additional blood samples will be required in this study beyond

the routine care. Maraviroc and lopinavir/ritonavir PEP may cause side effects. The most common side effects are gastrointestinal (digestive) symptoms, but these are unlikely to require any action since the treatment is only given for short time. The study doctor will advise patients on the appropriate management of any side effects. Maraviroc has not ever been used as a part of HIV PEP so its effectiveness has not been documented, and any potential risks will be monitored and the study stopped if necessary.

Where is the study run from?
The Mortimer Market Centre, Camden Provider Services, London
The Claude Nicol Unit, Brighton and Sussex University Hospitals NHS Trust, Brighton
The John Hunter Clinic, Chelsea and Westminster NHS Foundation Trust, London
The Lydia Clinic, St Thomas' Hospital, London

When is the study starting and how long is it expected to run for?
October 2011 to June 2013.

Who is funding the study?
Global Investigator Initiated Research Group, Pfizer

Who is the main contact?
Dr Paul Benn

# Contact information

### Type(s)
Scientific

### Contact name
Dr Paul Benn

### Contact details
Mortimer Market Centre
Off Capper Street
London
United Kingdom
WCE 6JB

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
MMC001

# Study information

## Scientific Title
Randomised controlled trial of the tolerability and completion of Maraviroc compared to Kaletra® in combination with Truvada® for HIV Post Exposure Prophylaxis

## Acronym
MiPEP

## Study objectives
This trial aims to determine whether maraviroc-based combination antiretroviral therapy (ART) is superior to a lopinavir (LPV) based combination, in terms of the proportion of patients who complete a full post exposure prophylaxis (PEP) course, and to compare clinical events, safety and toxicity between the two groups.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1 .NRES Committee London - Riverside ref: 11/LO/1333
2. NHS Brighton and Hove

## Study design
Multicentre open-label randomised study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Prevention

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

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

## Interventions
Control arm:
Patients randomised to the control arm will receive 28 days treatment with Truvada® (tenofovir disoproxil - as fumarate, 245 mg, emtricitabine 200 mg), one tablet once daily in addition to Kaletra® (lopinavir 200 mg, ritonavir 50 mg), two tablets twice daily. These drugs are the standard combination currently in use in most centres for PEP in the UK.

Experimental arm:
Patients randomised to the experimental arm will receive 28 days treatment with Truvada®

(tenofovir disoproxil -as fumarate- 245 mg, emtricitabine 200 mg), one tablet once daily in addition to maraviroc (300 mg), one tablet twice daily.

### Intervention Type
Drug

### Phase
Phase IV

### Drug/device/biological/vaccine name(s)
Tenofovir/emtricitabine, maraviroc, lopinavir/ritonavir

### Primary outcome measure
1. Composite end point of completion of 28 days of allocated PEP regimen without Grade 3 or 4 clinical or laboratory adverse events
2. Division of AIDS table for Grading the severity of Adult and Paediatric Adverse Events

### Secondary outcome measures
1. Completion rates of 28 days of allocated PEP regimen
2. Rates of Grade 1, 2, 3 or 4 clinical adverse events
3. Rates of Grade 1, 2, 3 or 4 laboratory anormalities
4. Rates and causes of regimen modification or discontinuation
5. Number of missed doses of Truvada® over 28 day course of PEP
6. Number of missed doses of Kaletra®or maraviroc over 28 day course of PEP
7. Number of doses of antidiarrhoeal medication taken
8. Number of doses of antiemetic taken
9. Number of days absent from work or college (not including days attending for clinic visits)
10. Number of clinic visits required
11. Rates of HIV seroconversion at month 4 after exposure
12. Proportion of individuals reporting unprotected anal/vaginal intercourse in
12.1. The three months preceeding PEP
12.2. While receiving PEP and
12.3. In the three months post completion of PEP with a potentially sero-discordant partner
13. Number of sexual partners in
13.1. The three month period preceeding PEP
13.2. While receiving PEP
13.3. The three month period following PEP
14. Rates of sexually transmitted infections [gonorrhoea, chlamydia, Lymphogranuloma venereum (LGV), syphilis, hepatitis B and C]

### Overall study start date
01/10/2011

### Completion date
01/06/2013

## Eligibility

### Key inclusion criteria

1. 18 years old or older
2. A patient attending one of four genitourinary medicine clinics and for whom PEP is considered appropriate by the clinician according to current guidelines including following occupational or non occupational exposure
3. Willing to provide written informed consent

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
280

### Key exclusion criteria
1. The baseline human immunodeficiency virus (HIV) test is reactive or positive
2. Currently receiving medication which would reduce the effectiveness of Kaletra® / maraviroc
3. Currently receiving medication where the interaction would result in a dangerously high level of the concomitant drug
4. Pregnant or trying to become pregnant at the time of trial entry
5. The source is known to have multi-drug resistant HIV and therefore more likely to have CXCR 4 tropic virus
6. History of active substance abuse or psychiatric illness that, in the opinion of the investigator, would preclude compliance with the protocol, dosing schedule or assessments
7. Any other active clinically significant condition, or findings during screening medical history or examination, or abnormality on screening laboratory blood tests that would, in the opinion of the investigator, compromise the patients safety or outcome in the trial

### Date of first enrolment
03/12/2011

### Date of final enrolment
31/05/2013

## Locations

### Countries of recruitment
United Kingdom

### Study participating centre

**Mortimer Market Centre**
Camden Provider Services
London
United Kingdom
WCE 6JB

**Study participating centre**
**The Claude Nicol Unit**
Brighton and Sussex University Hospitals NHS Trust
Brighton
United Kingdom
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**Study participating centre**
**The John Hunter Clinic**
Chelsea and Westminster NHS Foundation Trust
London
United Kingdom
-

**Study participating centre**
**The Lydia Clinic**
St Thomas' Hospital
London
United Kingdom
-

# Sponsor information

**Organisation**
Central and North West London NHS Foundation Trust (UK)

**Sponsor details**
c/o Ms Angela Williams
Camden Provider Services
Bedford House
125 - 133 Camden High Street
London
England
United Kingdom
NW1 7JR

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.cnwl.nhs.uk/

**ROR**
https://ror.org/05drfg619

# Funder(s)

**Funder type**
Industry

**Funder Name**
Pfizer (UK) ref: WS923309

**Alternative Name(s)**
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

**Funding Body Type**
Government organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United States of America

# 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? |
|---|---|---|---|---|---|

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|---|---|---|---|---|---|
| Results article | results | 01/06/2017 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |