

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	<input type="checkbox"/> Prospectively registered
Registration date 09/03/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/02/2018	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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 abnormalities
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 preceding 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 preceding 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]

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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Sponsor information

Organisation

Central and North West London NHS Foundation Trust (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, Pfizer Inc

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2017		Yes	No
HRA research summary			28/06/2023	No	No