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Pre-exposure option for reducing HIV in the UK: an open-label randomisation to immediate or deferred daily Truvada for HIV-negative gay men

Submission date
28/02/2013

Recruitment status
No longer recruiting

Registration date
28/02/2013

Overall study status
Completed

Last Edited
13/12/2019

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
Human immunodeficiency virus (HIV) is a virus that attacks the immune system and weakens the body's ability to fight infections and disease. It is most commonly caught by having sex without a condom. The aim of this study is to assess what happens when a new approach, known as pre-exposure prophylaxis (PrEP), is added to the existing methods available to gay men in the UK to reduce their risk of catching HIV. Prophylaxis is taking a drug to prevent, or at least reduce the risk of, catching an infection. In this study a drug called Truvada is used, which is commonly used to treat HIV. It is a combination of tenofovir and emtricitabine in a single pill, to be taken once a day. A major concern about HIV-negative individuals taking PrEP is that they will decrease their use of other methods such as condoms, thereby increasing their risk of HIV and other sexually transmitted infections. This can only be assessed when people know they are taking an active drug. This study therefore offers people PrEP on an 'open label' basis, meaning that everyone who takes it knows they are taking the drug; no-one takes an inactive placebo pill.

Who can participate?
HIV-negative gay men aged 18 or over

What does the study involve?
In order to assess what happens when PrEP is used, one group of participants needs to be followed for a period before using PrEP, at a time when they are accessing the best available methods for reducing risk. To do this, participants are randomly allocated to be offered PrEP either immediately or after 12 months. All participants are offered other interventions to reduce their risk. They are followed up in clinic every 3 months for 2 years, and tested for HIV. A test for sexually transmitted infections is carried out every 6 months or more frequently if indicated. In between visits, participants are asked to complete a diary and monthly questionnaire reporting anal intercourse and their pill taking when they are on Truvada.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Medical Research Council Clinical Trials Unit (MRC CTU) (UK)

When is the study starting and how long is it expected to run for?
November 2012 to October 2016

Who is funding the study?
1. Gilead Sciences (USA)
2. Health Protection Agency (HPA) (UK)
3. Medical Research Council (MRC) (UK)

Who is the main contact?
Dr Sheena McCormack
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Study website
http://www.proud.mrc.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2012-002373-56

IRAS number

ClinicalTrials.gov number
NCT02065986

Secondary identifying numbers

13131

Study information

Scientific Title
PRe-exposure Option for reducing HIV in the UK: an open-label randomisation to immediate or Deferred daily Truvada for HIV-negative gay men

Acronym
PROUD

Study objectives
The aim of this study is to assess what happens when a new approach, known as pre-exposure prophylaxis (PrEP), is added to the existing methods available to gay men in the UK to reduce their risk of catching human immunodeficiency virus (HIV) infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 02/10/2012, ref: 12/LO/1289

Study design
Randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions
A major concern about HIV-negative individuals taking PrEP is that they will decrease their use of other methods such as condoms, thereby increasing their risk of HIV and other sexually transmitted infections. This can only be assessed when people know they are taking an active drug. This study will therefore offer people PrEP on an 'open label' basis, meaning that everyone who takes it will know they are taking the drug; no-one will take an inactive placebo pill. In order

to assess what happens when PrEP is added, one group will need to be followed for a period before the PrEP is included, at a time when they are accessing the best available methods for reducing risk. To do this, the volunteers will be randomised to either be offered PrEP immediately or after 12 months. This study will use a drug called Truvada, which is commonly used to treat HIV. It is a combination of tenofovir and emtricitabine in a single pill, to be taken once a day. All participants will be offered other interventions to reduce their risk. They will be followed in clinic every 3 months for 2 years, and tested for HIV. A screen for sexually transmitted infections will be done every 6 months or more frequently if indicated. In between visits, participants will be asked to complete a diary and monthly questionnaire reporting anal intercourse and their pill taking when they are on Truvada.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Truvada

Primary outcome measure
Time to accrual; Timepoint(s): time to accrual of 500 participants

Secondary outcome measures
No secondary outcome measures

Overall study start date
29/11/2012

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. Born to male gender, age 18 years or more
2. Previously attended the enrolling clinic on at least one occasion
3. Completed a screen for HIV and sexually transmitted infections (STIs)
4. HIV negative by a routinely used assay within 4 weeks prior to or on the day of randomisation
5. Reported unprotected anal intercourse (UAI) on more than one occasion within the 90 days prior to randomisation
6. Likely, in the opinion of the volunteer, to have UAI in the next 90 days
7. Willing and able to comply with the visit schedule throughout the follow-up period
8. Willing and able to provide written informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
UK Sample Size: 500

Key exclusion criteria
1. An acute viral illness that could be due to HIV seroconversion
2. Any contraindications to Truvada according to the current package insert
3. Treatment for hepatitis B infection indicated or ongoing
4. Unlikely, in the opinion of the clinician, to comply with the randomised allocation

Date of first enrolment
29/11/2012

Date of final enrolment
28/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC CTU
London
United Kingdom
WC2B 6NH

Sponsor information

Organisation
Medical Research Council Clinical Trials Unit (MRC CTU) (UK)

Sponsor details
Aviation House
125 Kingsway
London
United Kingdom
WC2B 6NH

Sponsor type
Research council

Website
http://www.ctu.mrc.ac.uk/

ROR
https://ror.org/001mm6w73

Funder(s)

Funder type
Industry

Funder Name
Gilead Sciences

Alternative Name(s)
Gilead, Gilead Sciences, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Health Protection Agency (HPA) (UK)

Alternative Name(s)
HPA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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	02/01/2016		Yes	No
Results article	results	24/03/2016		Yes	No
Results article	results	10/12/2019	13/12/2019	Yes	No
HRA research summary			28/06/2023	No	No