AMPrEP (Amsterdam PrEP project)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22706

Source
NTR

Brief title
AMPrEP (Amsterdam PrEP project)

Health condition

HIV; prevention; Pre-exposure prophylaxis

Sponsors and support

Primary sponsor: Academic Medical Center is sponsor. Center for study visits: Public Health service Amsterdam (GGD Amsterdam)
Source(s) of monetary or material Support: GGD Amsterdam; AIDS fonds; RIVM; Gilead sciences; H-team funders (Janssen; BMS; ViiV; Amsterdam Diner Foundation)

Intervention

Outcome measures

Primary outcome

To investigate the uptake, acceptability and usability of a comprehensive HIV infection prevention program for high-risk MSM through 2 different intervention strategies: daily PrEP and on demand PrEP, combined with intensified standard care at the PHSA.

Secondary outcome

A. Adherence

To assess the adherence of the participants to medication schedules and follow-up regimes

To assess factors predicting adherence

To assess barriers for adherence

To assess the number of attended scheduled clinic visits

B. Adverse events

To assess the incidence of serious adverse reactions attributable to the antiretroviral medication

To assess the incidence of adverse events that lead to interruption or cessation of antiretroviral medication

To assess changes in renal function

C. HIV infection

To assess the HIV incidence rate in the two project arms

D. Viral resistance

To assess HIV-drug resistance in case of incident HIV infection

E. Risk behaviour

To assess trends in self-reported risk behaviour

F. STIs

To determine trends in incidence rate of STIs

G. Barriers and motives of choice of intervention

To identify barriers and motives of choice of intervention and participant satisfaction with

their choice

H. General well-being

To assess self-perceived health and psychosocial well-being including sexual health

Study description

Background summary

Hypothesis: Public Health Service of Amsterdam (PHSA) can inform HIV-negative men who have sex with men (MSM) at high risk for HIV infection about and provide them with daily or intermittent pre-exposure prophylaxis (PrEP), to be taken as part of a comprehensive HIV risk reduction package. MSM can adequately make a choice between the two different intervention strategies and adhere to the chosen strategy. This comprehensive HIV prevention program has a good acceptability, feasibility and usability.

Objective: To investigate the uptake, acceptability and usability of a comprehensive HIV infection prevention program for high-risk MSM through 2 different intervention strategies (i.e. daily or intermittent PrEP) at the PHSA.

Study design: Evaluation study of a demonstration project of 2 different HIV prevention strategies (daily or intermittent PrEP), as part of a comprehensive HIV prevention program. Study population: Men who have sex with men at increased risk for HIV (i.e. diagnosed with syphilis, urethral or rectal chlamydia or gonorrhoea within the last six months, reporting unprotected anal intercourse (UAI) with casual partners within the last six months, received PEP within last six months or having a HIV positive partner with unknown or detectable viral load in the last six months).

Intervention: Demonstration project with two arms: one group will receive daily PrEP and the second group will be provided with intermittent PrEP (i.e. 2 tablets between 24 and 2 hours before sexual contact followed by one tablet every 24 hours until 48 hours after the last sexual contact). After counselling, participants can choose an intervention. In addition, participants are allowed to switch between arms.

Main study parameters/endpoints: We will investigate uptake, acceptability, and usability of daily and intermittent PrEP, medication adherence, adverse events, behavioural disinhibition (i.e. increase in risk behaviour and in incidence of STIs), HIV infection and resistance.

Timeline: Start inclusion1 August 2015. End of inclusion: 1 November 2017. End of study interventions: 1 June 2018. End of follow-up: 1 December 2018.

Study objective

Public Health Service of Amsterdam (PHSA) can inform HIV-negative men who have sex with men (MSM) at high risk for HIV infection about and provide them with daily or intermittent pre-exposure prophylaxis (PrEP), to be taken as part of a comprehensive HIV risk reduction package. MSM can adequately make a choice between the two different intervention strategies and adhere to the chosen strategy. This comprehensive HIV prevention program has a good acceptability, feasibility and usability.

Study design

end 2016: baseline characteristic and interim analyses

end 2020: final evaluation

Intervention

Daily or Intermittent PrEP (modality at choice of participant)

Contacts

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Eligibility criteria

Inclusion criteria

All of the following:

1. Male or transgender, age 18 years or more

2. MSM

3. Completed HIV and STI screening

4. HIV negative by 4th generation Elisa antigen/antibody test.

5. Willing and able to comply to project visit schedule and procedures

6. Willing and able to give written informed consent

7. Sufficient understanding of Dutch or English

AND at least one of the following:

1. One or more documented STI (urethral or anal chlamydia or gonorrhoea, primary or secondary syphilis) in the last 6 months (either at STI clinic or a documented infection diagnosed elsewhere)
2. UAI with casual partners in the last 6 months

3. Received PEP after sexual risk incident in the last 6 months

4. HIV positive partner with unknown or detectable viral load

Exclusion criteria

One of the following:

1. Signs or symptoms of acute HIV infection1

2. Hepatitis B infection (i.e. HbsAg positive)

3. Creatinine clearing (using cockroft gault formula) < 60 ml/min

4. Concurrent use of nephrotoxic medication (aminoglycosides, amphotericin B, foscarnet,

ganciclovir, pentamidine, vancomycin, cidofovir or interleukin-2)

5. Hypersensitivity for one of the components of fixed combination tablet containing tenofovir and emtricitabine2

6. Unlikely, in the opinion of the clinician, to comply with trial schedule

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-08-2015
Enrollment:	370
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	24-08-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5302
NTR-old	NTR5411
Other	METC AMC : 2014_407

Study results