AMPrEP (Amsterdam PrEP project)

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22706

Bron
NTR

Verkorte titel
AMPrEP (Amsterdam PrEP project)

Aandoening

HIV; prevention; Pre-exposure prophylaxis

Ondersteuning

Primaire sponsor: Academic Medical Center is sponsor. Center for study visits: Public Health service Amsterdam (GGD Amsterdam)
Overige ondersteuning: GGD Amsterdam; AIDS fonds; RIVM; Gilead sciences; H-team funders (Janssen; BMS; ViiV; Amsterdam Diner Foundation)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

end 2016: baseline characteristic and interim analyses

end 2020: final evaluation

Onderzoeksproduct en/of interventie

Daily or Intermittent PrEP (modality at choice of participant)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	03-08-2015
Aantal proefpersonen:	370
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	24-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten