Biomedical interventions for HIV prevention in MSM in Amsterdam: a demonstration project

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON42253

Source
ToetsingOnline

Brief title
AMPrEP: Amsterdam PrEP program

Condition

- Viral infectious disorders

Synonym
pre-exposure prophylaxis, Prevention of HIV infection with medication

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: GGD;mogelijk Pharmaceutische bedrijven;andere fondsen,Gilead Sciences

Intervention

Keyword: HIV, Men who have sex with men, Pre-exposure prophylaxis, Prevention

Outcome measures

Primary outcome

To study acceptability, feasibility and uptake of PrEP

Secondary outcome

Secundary endpoints are: medication adherence, side effects, incidence of hiv

and viral resistance in case of incident HIV infection, changes in risk

behaviour and changes in STI prevalence.

Study description

Background summary

Anno 2014 in the Netherlands, HIV spreads mainly among men who have sex with men (MSM). The numbers of new HIV infections in this group remain high: of the 1051 new HIV infections, 700 concerned MSM (Source: Stichting HIV Monitoring report 2013). The trend of a slightly increasing and ongoing HIV transmission has been visible since 1996 when effective combination antiretroviral therapy became available. This transforms HIV from a fatal disease into a chronic disease. New prevention strategies are therefore needed to limit transmission of HIV.

The effectiveness of a new biomedical intervention for HIV negative risk groups, pre-exposure prophylaxis (PrEP), was recently described in the international literature: it provides additional protection against HIV infection. This iPrEx study (Grant RM et al, N Engl J Med 2010), showed that Truvada (tenofovir disoproxil fumarate and emtricitabine), if given to HIV-negative MSM with high-risk behavior, decreased the risk of HIV seroconversion with 44%, and in those with good compliance, protection increased to 92%. The open label follow-up study iPrEx OLE reported not only a risk reduction for HIV infection which was dependent of drug levels in blood.

So PrEP has proven efficacy in research settings to prevent hiv infections in prioritized populations such as MSM. Centers of Disease Control and Prevention (CDC) in de US and the World Health Organization state that PrEP is/should be

part of a comprehensive hiv prevention program.

Two important points need attention in PrEP provision: adherence and risk disinhibition.
Adherence has been inadequate in some studies (VOICE, FEM-PREP), rendering the effect negligible.
Earlier research showed more risk behaviour after hiv therapy became available. IPrEx and iPrEx OLE however, did not report this finding. Before PrEP is implemented in standard care, we have to exclude that an increase in risk behaviour causes PrEP to be of little effect.

Study objective

The objective of this project is to investigate uptake, usability and acceptability of two hiv prevention interventions. These relate to the use of biomedical interventions, ie the provision of daily and intermittent PrEP to men who have sex with men with additional risk factors for an HIV infection..

The hypotheses are as follows: to investigate whether Public Health Service Amsterdam (PHSA) can inform HIV-negative men who have sex with men (MSM) at high risk for HIV infection about and provide them with pre-exposure prophylaxis (PrEP) to be taken as part of a comprehensive HIV risk reduction package.To investigate whether MSM can adequately make own choice between two different intervention strategies and adhere to the chosen strategy. To investigate whether this comprehensive HIV prevention program has a good uptake, acceptability and usability.

Study design

Evaluation of a demonstration project of 2 different intervention strategies for MSM with additional risk factors for HIV infection

Intervention

1. daily Pre-exposure prophylaxis
2.intermittent pre-exposure prophylaxis

Study burden and risks

Burden: 4 times per year a 30-minute visit of the STI clinic, for STI and HIV screening, involving venapunction to draw 25 ml of blood. A computer-based questionnaire about health including sexual health, burden of project requirements, number of sex partners, number of comdom-protected and unprotected sex acts. Keeping a diary on (un)protected sex acts. No risks.

Taking one Truvada pill daily or intermittent. Keep diary of therapy adherence.

Truvada is a safe drug, on the market for HIV treatment since 2004. Moderate risk of mild side effects, very small risk of more severe side effects such as kidney problems.

Benefits:: increased frequency of screening for HIV infection and STI: earlier treatment is possible.
Additional protection for HIV by PrEP (as proven in earliers studies, around 44% up to 92% extra risk reduction)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

see below

Exclusion criteria

One of the following:1. Signs or symptoms of acute HIV infection2. Hepatitis B infection (i.e. HbsAg positive)3. Unlikely, in the opinion of the clinician, to comply with project schedule4. Hypersensitivity for one of the components of fixed combination tablet containing tenofovir and emtricitabine5. Creatinine clearing using cockroft gault formula: < 60 ml/minrolegroepContr

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

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

Medical products/devices used

Product type:	Medicine
Brand name:	Truvada
Generic name:	emtricitabine + tenofovir
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	23-04-2015

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2019

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2014-002569-32-NL
CCMO	NL49504.018.14