A study in HIV discordant partnerships to estimate the rate of transmission of HIV and to investigate factors associated with condom use.

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We aim to follow serodifferent partnerships who initially report recently having had unprotected sexual intercourse in order to study (i) the risk of HIV transmission to partners, in particular in partnerships that continue not to use condoms...

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

Summary

ID

NL-OMON34254

Source
ToetsingOnline

Brief title
Partners of people on ART: a New Evaluation of the Risks
PARTNER study

Condition

- Viral infectious disorders

Synonym
HIV-1

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Copenhagen HIV Programme

Intervention

Keyword: HIV-1, sero-discordant, transmission

Outcome measures

Primary outcome

The primary analysis will be estimation of the rate of infection in partners per person year of unprotected sex partnership where the index patient has viral load <50 c/mL, excluding new infections that are shown to be phylogentically distinct from the HIV positive partner*s virus; i.e. transmission has not been from the HIV positive partner. This will be calculated as the number of infections identified at the end of eligible periods divided by the sum of the person time over eligible periods (see below for definition of eligible periods).

Secondary outcome

In secondary analyses we will also estimate
(i) the rate of infection in partners per unprotected sex act where index patient has viral load < 50 c/mL, as opposed to per person year (this will be done by summing numbers of acts of anal and vaginal intercourse over eligible periods)
(ii) the rate of infection if we replace 50 copies/mL by 200 copies/mL in the above definition and
(iii) the rate of transmission if we insist that the next viral load value in

the HIV positive partner after the end of the period is also < 50 copies/mL,

(iv) the rate of transmission if we consider periods to be eligible if only

oral sex is reported,

(v) the rate of transmission if we ignore viral load measures made on the HIV

positive partner which are within 4 weeks of the end of the period (because of

the lag time in obtaining a result).

We will assess the proportion of partnerships that begin to adopt consistent

condom use (ie reporting by both partners of 100% of episodes of sexual

intercourse in which a condom was used) and assess factors associated with this

using logistic regression.

Study description

Background summary

It is consistently reported that a proportion of people with diagnosed HIV do not always use a condom when having sexual intercourse with partners of negative or unknown HIV status. There are likely to be many reasons for this, and these reasons may have changed over time. It is important to study HIV serodifferent partnerships (where one partner is HIV positive and the other HIV negative) that report having unprotected sex to understand the reasons why condoms are not used, and to see what factors are associated with partnerships beginning to adopt consistent condom use. Increasingly, one reason for not using condoms is likely to be due to the person being on antiretroviral therapy with the plasma viral load being < 50 copies/mL, and statements on the likely reduced infectiousness of people in this situation have been issued (1,2). There is increasingly strong evidence that virally suppressive ART reduces infectiousness of people with HIV through sex (1-21). However, precise estimates of this risk of transmission from unprotected intercourse when the infected person is on ART with a most recent plasma viral load < 50 copies/mL are not available, particularly for men who have sex with men (MSM). It is extremely important that more precise estimates are obtained, both for counselling purposes, and for investigations into the potential prevention

effects of a policy of expanding ART coverage to be offered to all people with diagnosed HIV.

It should be noted that while levels of HIV viral load in plasma are measured as part of patient clinical care, levels of HIV in genital fluids are likely to be more relevant for sexual transmission. The two are highly correlated and antiretroviral therapy markedly reduces levels of HIV in semen (22-39), but detectable levels of HIV RNA have been found in genital fluids among those with plasma viral load, which is < 50 c/mL (40). Intercurrent sexually transmitted infections can lead to a transient increase in viral load in the genital compartment that could increase transmission risk temporarily (41). It should also be noted that detectable levels of infectious virus being present in semen or other genital fluids does not necessarily equate to the person being infectious since presence of drug in the same fluid may act to prevent infection of cells in the partner.

Study objective

We aim to follow serodifferent partnerships who initially report recently having had unprotected sexual intercourse in order to study (i) the risk of HIV transmission to partners, in particular in partnerships that continue not to use condoms consistently and the HIV-positive partner is on therapy with a viral load < 50 copies/mL and (ii) why some partnerships do not use condoms, to describe the proportion who begin to adopt consistent condom use, and factors associated with this.

Study design

This is an observational study in which HIV serodiscordant partnerships will be followed over time, with 3-6 monthly reporting of transmission risk behaviour and HIV testing for the HIV negative partner.

Study burden and risks

HIV positive partner

At baseline visit
To sign a consent for participation in the study, in which the partner is identified by name and date of birth
To complete a baseline risk behaviour questionnaire (approximately 15 mins)

At each clinic follow-up visit while the partner remains under follow-up
To complete a follow up risk behaviour questionnaire (approximately 15 mins)

If HIV negative partner becomes infected with HIV:
To provide an additional blood sample so that virus can be compared anonymously

with that of the newly infected HIV negative partner

HIV negative partner

At baseline visit
To attend clinic (with or separately from the HIV positive partner) and sign consent for participation in the study, in which the partner is identified by name and date of birth
To test for HIV
To complete a baseline risk behaviour questionnaire (approximately 15 mins)

At 3-6 monthly intervals after the baseline visit
To complete a follow up risk behaviour questionnaire (approximately 20 mins)
To test for HIV
Note that the HIV negative partner has to fill out the questionnaire before receiving the HIV test result

If becomes infected with HIV:
To provide an additional blood sample so that virus can be compared anonymously with that of the HIV+ partner

Length of follow-up
We anticipate the study will take 1.5 years in order to recruit to the cohort. Partnerships will be followed for 2 years.

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

Inclusion criteria
- Confirmed HIV positive
- On ART (regardless of viral load)
- Age > 18
- Expected to remain under care at the clinic for as long as the participate in the study ;Has a partner not known to be HIV infected and the following criteria are met:
- The partners have had unprotected penetrative anal or vaginal intercourse together in the past month (during which period the HIV negative partner was aware of the HIV status of the HIV positive partner)
- The partners expect to have sex together again in the coming months
- Both partners consent to attend clinic to complete a risk behaviour questionnaire every 3-6 months for as long as they participate in the study.
- The HIV negative partner consents to testing for HIV at these visits.
- Both partners consent to provide a separate blood sample if the HIV negative partner should become infected with HIV (this is for an anonymous comparison of viruses * results will not be linked to the partnership)

Exclusion criteria

Pregnancy. (Only upon inclusion, if a woman (whether the negative or the positive partner) becomes pregnant during the study, then the partnership can continue in the study, if they wish to do so).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
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
CCMO	NL33075.018.10