Assessment of risk behaviour in HIV-infected men

Published: 29-03-2013
Last updated: 26-04-2024

Objective: General objective: To improve and standardize assessment of risk behaviour and its behavioural correlates in HIV patients. Specific objectives: 1) To assess sexual risk behaviour in HIV patients, 2) to assess drug related risk behaviour...

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37303

Source
ToetsingOnline

Brief title
TRINITAS

Condition

- Viral infectious disorders
- Impulse control disorders NEC
- Lifestyle issues

Synonym
HIV

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: geen financiering. Het onderzoek wordt verricht binnen de context van de dagelijkse behandelpraktijk en de academische functie van

het UMC St. Radboud. Aanvullende financiering is niet vereist.

Intervention

Keyword: HIV, impulse control, risk behaviour

Outcome measures

Primary outcome

Main study parameters/endpoints: Risk behaviour as assessed by self report questionnaires, and impulse control as assessed by self report questionnaires and standardized computer tasks.

Secondary outcome

NA

Study description

Background summary

Rationale: Human Immunodeficiency Virus (HIV) infection is a serious condition, that leads to decreased immune function in humans. The virus is transmitted through blood or sexual contact between humans. As such, unprotected sex or sharing needles for intravenous drug use can be considered risk behaviour that contributes to the spreading of HIV. Moreover, such risk behaviour increases the risk of blood born or sexually transmitted co-infections, which in turn negatively affects the prognosis of HIV patients.
Therefore, it is very important to assess risk behaviour in patients infected with HIV, to identify key populations contributing to the spreading of HIV and those at risk for fast disease progression, for both preventive and curative interventions. However, the current practice of the assessment of risk behaviour is in a qualitative way. The present study is a first exploration of risk behaviour and its correlates in HIV patients, currently in treatment, using a standardized assessment battery, as it is in use in the department of psychiatry.

Study objective

Objective: General objective: To improve and standardize assessment of risk behaviour and its behavioural correlates in HIV patients. Specific objectives:

1) To assess sexual risk behaviour in HIV patients, 2) to assess drug related risk behaviour in HIV patients, 3) to assess the relation between risk behaviour and impulse control in HIV patients.

Study design

Study design: In an observational pilot study, risk behaviour and impulse control will be assessed as part of the treatment as usual.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Burden and risk of participation consist of the time spent on filling in the questionnaires (approximately two times 30-45 minutes) and the time spent on the computer tasks (30-45 minutes). Risks are neglible and the burden is considered to be minimal. The results of the questionnaires and computer tasks will inform the patient and their caregiver (doctor and nurse). The information on risk behaviour and impulse control can be used in patient education on risk behaviour in HIV, as part of treatment as usual.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 10
Nijmegen 6525 GC
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 10
Nijmegen 6525 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male HIV patients (N=100) that are in treatment at the outpatient department for HIV of the Radboud University Nijmegen Medical Centre will be recruited.

Exclusion criteria

Exclusion criteria are age below 18 or above 60 years, difficulty with Dutch language, severe physical illness, suspicion of current mental illness, interfering with informed consent.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-03-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL41407.091.12