# Assessment of risk behaviour in HIVinfected 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

NI

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