Testosterone insufficiency in human immunodeficiency virus (HIV) infected women

Published: 13-11-2007
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To explore the prevalence of testosterone insufficiency in HIV-infected women and the associated sexual problems, fatigue , depression and quality of life.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32221

Source
ToetsingOnline

Brief title
TI-study

Condition

- Other condition

Synonym
testosterone deficiency among HIV infected women

Health condition

Mogelijke insufficientie van testosteron bij HIV infectie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hiv infected women, insufficiency, testosterone

Outcome measures

Primary outcome

Hormones: testosteron and SHBG

Secondary outcome

Questionnaires: FSFI, FSDS, SF36/MFI-20, SCL-90.

Study description

Background summary

Little is known about the prevalence of testosterone insufficiency and the associated problems in HIV-infected women. Among HIV infected men is the correlation between testosterone insufficiency and the associated factors described. The treatment in these men is effective.

Study objective

To explore the prevalence of testosterone insufficiency in HIV-infected women and the associated sexual problems, fatigue , depression and quality of life.

Study design

A cross-sectional design.

Study burden and risks

Because the extra blood will taken at the same moment as the standard blood we expect no extra risks. The questionnaire will take 30 minutes.

Contacts

Public
Academisch Medisch Centrum

meibergdreef 9
1105 AZ amsterdam
Nederland
Scientific
Academisch Medisch Centrum

meibergdreef 9
1105 AZ amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Female
HIV-infected
At least 18 year of age
Able and willing to provide informed consent
Understanding of Dutch or English language

Exclusion criteria

Androgen therapy during the 6 months prior to study start
Lactation and/or pregnancy in the 6 months prior to study start
Thyroid disease; hypo * or hyperthyroidism

Inability to understand questionnaire
Transgender hormonal/surgical therapies in past
Ovariectomy or radiation of the ovaries

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2007
Enrollment:	80
Type:	Anticipated

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	NL20222.018.07