Osteoporosis and Activation Study of the Immune System in HIV

Published: 25-06-2014
Last updated: 20-04-2024

In this exploratory pilot study, we aim to investigate the role of immune activation in osteoporosis in HIV-infected patients on HAART with proven osteoporosis/ osteopenia in comparison to HIV-infected patients on HAART without osteoporosis/...

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

Summary

ID

NL-OMON40958

Source
ToetsingOnline

Brief title
OASIS-HIV

Condition

- Viral infectious disorders
- Bone disorders (excl congenital and fractures)

Synonym
Osteoporosis, Porous bones

Research involving
Human

Sponsors and support

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

Intervention

Keyword: HIV, Immune activation, Osteoporosis

Outcome measures

Primary outcome

• the level of T cell activation will be compared between the HIV-infected patients with osteoporosis/ osteopenia and those without osteoporosis/ osteopenia.

Secondary outcome

Secondary endpoints:

• the concentration of cytokines involved in the immunopathology of osteoporosis

• the expression of collagen markers

All endpoints will be compared between the HIV-infected patients with osteoporosis/ osteopenia and those without osteoporosis/ osteopenia.

Study description

Background summary

The prevalence of osteoporosis in HIV-infected patients is increased 3.7 fold compared to non HIV-infected, age-matched individuals. Besides traditional risk factors, HIV-specific risk factors also seem to play a role, such as Highly Active Anti-Retroviral Therapy (HAART) and immune activation. Immune activation has been implicated as the driving force in several non-AIDS defining diseases which we see nowadays in HIV-infected patients. The level of immune activation can be measured by investigating T cell activation and other cellular and soluble markers. In osteoporosis patients, T cell activation and the presence of certain cytokines has not been studied extensively. By examining the level of T cell activation in HIV-infected patients with osteoporosis, compared to HIV-infected patients without osteoporosis, a better understanding of the

contribution of immune activation to osteoporosis can be studied.

Study objective

In this exploratory pilot study, we aim to investigate the role of immune activation in osteoporosis in HIV-infected patients on HAART with proven osteoporosis/ osteopenia in comparison to HIV-infected patients on HAART without osteoporosis/ osteopenia.

Study design

A single visit, cross-sectional exploratory pilot study.

Study burden and risks

Single visit study, with blood draw of 3 vials, a total of 27ml. Subjects will not benefit individually from participating in this study. However, group-related benefits include an understanding of the level of T cell activation and immune cytokine expression related to the presence of osteoporosis in HIV-infected patients.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Successful participation in the *A Phase 4 Cross-Sectional Study of Bone Mineral Density in HIV-1 Infected Subjects* study (UMCU METC number 13-429):
- HIV-1 infected subjects regardless of race or ethnicity.
- Use of one of the following taken as a stable, continuous, NRTI-containing ARV regimen for >= 3 years are allowed (within-class change of agents other than TDF within 3 years of study entry are permitted as specified):
- a TDF plus PI/r-containing regimen including subjects who switched from one TDF plus PI/r regimen to another TDF plus PI/r regimen.
- a TDF plus non-PI/r-containing regimen including subjects who switched from one TDF plus non-PI/r regimen to another TDF plus non-PI/r regimen.
- a Non-TDF NRTI plus a PI/r-containing regimen including subjects who switched from one non-TDF NRTI plus PI/r regimen to another non-TDF NRTI regimen plus PI/r regimen.
- a Non-TDF NRTI plus a non-PI/r-containing regimen including subjects who switched from one non-TDF NRTI plus non-PI/r regimen to another non-TDF NRTI regimen plus non-PI/r regimen.
- Male subjects must be >= 50 years of age.
- Female subjects must be postmenopausal.
- Adequate records available to evaluate medical history prior to study entry, including:
- prior ARVs and other medications
- risk factors for osteoporosis and osteopenia
- Able to give informed consent, which must be obtained prior to initiation of any study procedures.

Exclusion criteria

None

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	25-06-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL47918.041.14