Role of periodontitis in accelerated ageing in HIV-infected patients

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1. Determine the relationship between periodontitis and HIV-related immune activation and hypercoagulability.2. Explore the role of oral microbiota as effect modificator of the relationship between periodontitis and immune activation in HIV-infected...

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

Summary

ID

NL-OMON40726

Source
ToetsingOnline

Brief title
ROPAAH

Condition

- Other condition
- Viral infectious disorders
- Embolism and thrombosis

Synonym
HIV infection, periodontitis

Health condition

mondgezondheid

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ageing, HIV, immune activation, periodontitis

Outcome measures

Primary outcome

Independent endpoints: Periodontal Inflamed Surface Area (PISA)

Dependent endpoints: markers of immune activation and hemostasis and

composition of the oral microbiota.

Secondary outcome

Content of the oral microbiome as effect modifier of the relationship between

the main study parameters.

Study description

Background summary

Rationale: Combination antiretroviral therapy (cART) is a spectacular success in the fight against HIV. However, the life expectancy of HIV-infected patients using cART is still >10 years shorter than that of uninfected persons. This is due to an increased risk of non-AIDS age-related co-morbidities, such as cardiovascular disease, malignancies and liver disease. Persistent immune activation, despite near-complete suppression of viral replication, is believed to be responsible. Immune activation independently predicts mortality in HIV-infected patients, but the mechanism behind HIV-related immune activation is still unclear. Translocation of microbial products into the blood in HIV-infected patients correlates with immune activation, suggesting an important role for a disturbed balance between the microbiota and the immune system. Current research has focused almost exclusively on the large intestine as the site of this translocation. An important alternative source of microbial translocation could be inflammation of the tooth-supporting tissues: periodontitis. This condition is characterized by a distinct composition of the

oral microbiota, and is strongly associated with age-related diseases. Indeed, markers of microbial translocation were found to be elevated in patients with periodontitis. Periodontitis is frequently observed in HIV-infected patients, but its role in HIV-related immune activation has not been studied. Notably, oral health is an often neglected topic by both HIV-infected patients and their doctors.

HYPOTHESIS
We hypothesize that chronic periodontitis contributes to systemic immune activation in HIV-infected patients despite viral suppression by disturbing the balance between oral microbiota and the immune system. Furthermore, we hypothesize that HIV-infected patients with chronic periodontitis are characterized by a hypercoagulable state. We presume that treatment of periodontitis will reduce systemic immune activation and risk of co-morbidities and thus could improve the life expectancy of HIV-infected patients.

Study objective

1. Determine the relationship between periodontitis and HIV-related immune activation and hypercoagulability.
2. Explore the role of oral microbiota as effect modificator of the relationship between periodontitis and immune activation in HIV-infected patients.

Study design

Phase 1: in a cross-sectional observational study we will determine the prevalence of periodontitis in HIV-infected patients visiting the UMCG outpatient clinic using the DPSI.

Phase 2: in a cross-sectional case-control study we will compare the Periodontal Inflamed Surface Area (PISA), markers of immune activation, hemostatic parameters and oral microbiota of 40 HIV-infected patients with periodontitis (DPSI >2; cases) and 40 HIV-infected patients without periodontitis (DPSI <=2; controls) selected from phase 1.

Study burden and risks

Other than standard care, subjects in Phase 1 will undergo a short screening of periodontal disease. Patients in Phase 2 additionally will undergo venous blood sampling, a brief questionnaire on dental hygiene and a more extensive assessment of periodontal disease (PISA). As part of this assessment a subgingival plaque sample will be obtained to identify the oral microbiota.

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

HIV-1 infection
use of combination antiretroviral therapy for >=6 months and last 2 viral loads <40 copies/ml or undetectable

Exclusion criteria

• Unable to understand spoken and written Dutch or English language
• History of radiation therapy in the head and neck region
• Edentulism

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	09-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL49922.042.14