

"HIV (ge) VAT" Vascular care in HIV infected patients; Reduction of vascular risks in HIV-1 infected patients

A pilot study

Published: 08-11-2007

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To study the impact of treating potentially modifiable vascular risk factors in HIV-1 infected patients by a nurse-led vascular intervention program

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON30870

Source

ToetsingOnline

Brief title

Vascular Care in HIV infected patients

Condition

- Viral infectious disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

Vascular risks

Research involving

Human

Sponsors and support

Primary sponsor: Alysis Zorggroep

Source(s) of monetary or material Support: eigen gelden, GlaxoSmithKline

Intervention

Keyword: HIV patients, reduction, Vascular risks

Outcome measures

Primary outcome

Nursing interventions, education and counselling based on self-management promotion can provide a new and promising approach to actually achieve vascular risk reduction in HIV infected patients.

Before the intervention the vascular risks will be performed with the SCORE.

Afterwards we will expect a reduction of the risk factors.

Secondary outcome

not applicable

Study description

Background summary

Since the introduction of HAART, HIV infection became a chronic disease. Together with promising therapy, metabolic side effects e.g. dyslipidemia and hyperglycemia are reported. This increases the risk of vascular diseases. Keystone of preventive measures include lifestyle modification which may improve morbidity and survival of other populations. Nurse-led interventions are cheaper and more effective than treatment by physicians. This however has not been shown yet in this particular population.

Study objective

To study the impact of treating potentially modifiable vascular risk factors in HIV-1 infected patients by a nurse-led vascular intervention program

Study design

A collaboration between the clinical nurse specialist of the HIV outpatient

clinic and the vascular nurse of the vascular outpatient clinic. HIV infected patients (naive and experienced with HAART) will be screened on vascular risk factors also related to metabolic syndrome. An increased risk of diseases are subjects to nurse-led vascular programs based on medical treatment, self-management promotion and lifestyle changes of these patients to reduce the risk of vascular diseases.

This is a pilot study and patients are randomised 1:1 in two groups, 1 intervention group and 1 control group.

Quality of Life will be measured in both groups at week 0 - 12 - 24 and 48

Intervention

During 12 months patients in the intervention group will be followed by the vascular nurse. She makes a plan together with the patient for lifestyle changes e.g. smoking cessation, regular exercise, healthy diets and if necessary medical treatment of the risk factors.

The vascular nurse provides support, encouragement and reassurance in changing or maintaining desired lifestyle and their adherence to prescribed therapy.

The patients in the control group get the standard of care by the clinical nurse specialist HIV.

Study burden and risks

not applicable

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Fasten glucose > 6.1 mmol/l

HDL chol < 1.0 mmol/l for men and < 1.3 mmol/l for women

Triglycerides > 1.7 mmol/l

Bloodpressure > 135/85 mm/Hg

Exclusion criteria

none

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	50

Type:

Anticipated

Ethics review

Approved WMO

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

NL18196.091.07