Follow-up of thrombophilia, inflammation and markers of cardiovascular disease of HIV-1 patients on longterm cART

Published: 26-06-2019
Last updated: 09-04-2024

1) to evaluate the effect of cART on markers of thrombophilia plasmalevels in hiv-infected patients2) to evaluate the long-term effect of cART on lipid spectrum3) to evaluate the incidence of venous thrombosis and cardiovascular events in hiv-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON47997

Source
ToetsingOnline

Brief title
INF-BEAST2

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Viral infectious disorders
- Embolism and thrombosis

Synonym
acquired thrombophilia, clotting disoder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: stichting afdeling stollingsziekten

Intervention

Keyword: cART, HIV, thrombophilia, venous thrombosis

Outcome measures

Primary outcome

Plasma-levels of anti-thrombin, protein C antigen, protein S antigen, free

protein S, fibrinogen, lupus anticoagulans, von Willebrand factor antigen,

D-dimer

Secondary outcome

hsCRP, CRP, cholesterol, HDL-, LDL-cholesterol, triglycerides and the

occurrence of venous thrombosis and cardiovascular events after almost 8 years

of cART.

Study description

Background summary

Epidemiological studies have demonstrated that people living with hiv have an increased risk of developing venous thrombosis and cardiovascular disease than the general population. The pathophysiology of thrombosis is a complex and multifactorial process, in which the balance of procoagulant and anticoagulant activity is disturbed causing a thrombophilic state. Several factors in hiv-infection contribute to a procoagulant state. Earlier studies have demonstrated a decrease in anticoagulant factors, e.g. protein S en C, and an increase in procoagulant factors, e.g. D-dimer, fibrinogen and von Willebrand factor (vWF). However, the pathophysiology of this thrombophilic state in hiv-infection remains to be elucidated. Several studies have demonstrated that the thrombotic risk in hiv-infection is associated with chronic immune-activation and inflammation. On the other hand, combination antiretroviral therapy (cART) is also associated with an increased risk of venous thrombosis and cardiovascular disease. Both the hiv-infection itself and its treatment could contribute to the thrombophilic state seen in hiv-infected patients.

In 2010, the INF-BEAST study was performed to evaluate the effect of cART in cART-naive hiv-infected. At start of cART, elevated levels of procoagulant factors and cardiovascular markers (i.e. the lipid profile) with decreased levels of anticoagulant factors were found. After a year of cART, a subtle decrease in procoagulant factors and cardiovascular markers was seen with an increase in anticoagulant factors. However, currently no data is available on the long-term effect of cART on the thrombophilic state in hiv patients. In this study we aim to determine the thrombophilic state and cardiovascular markers in the INF-BEAST patient population after almost eight years of treatment with cART.

Study objective

1) to evaluate the effect of cART on markers of thrombophilia plasmalevels in hiv-infected patients
2) to evaluate the long-term effect of cART on lipid spectrum
3) to evaluate the incidence of venous thrombosis and cardiovascular events in hiv-infected patients on longterm cART.

Study design

A prospective cohort study

Study burden and risks

Patients who participated in the INF-BEAST study in 2010 will be re-invited for the INF-BEAST2 study. After giving informed consent, the participant will be invited once for the study procedures. First, a standardized questionnaire will be conducted regarding medical history, risk factors for venous thrombosis, cardiovascular disease and medication use. This will take ten to fifteen minutes. Secondly, one peripheral venous puncture will be performed in order to sample blood. The sampling of blood for this study will be combined with routine follow-up blood testing necessary for the hiv-treatment as much as possible in order to avoid extra punctures. An extra 12 mL will be sampled. The study visit will be combined with routine follow-up appointments at the department of Infectious Diseases or other specialists in the UMCG, as much as possible. However, not all participants of the INF-BEAST study are still in follow-up at the UMCG. For these patients participation to this study might mean an extra visit and venous puncture.
The participants will not benefit from participation to this study, neither will they be exposed to any risks as no risks are known from sampling an 12 mL extra blood via venous puncture.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Participation in the INF-BEAST study

Exclusion criteria

No informed consent provided for participation in INF-BEAST2

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):	15-07-2019
Enrollment:	39
Type:	Actual

Ethics review

Approved WMO

Date:	26-06-2019
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	NL68880.042.19