Coagulation parameters in HIV

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20034

Source
Nationaal Trial Register

Brief title
INF-BEAST2

Health condition

HIV, thrombophilia

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Plasma levels of following markers:
- FVIII
- Anti-thrombin
- Protein C antigen
- Protein S antigen
- Free protein S
- Fibrinogen

- Lupus anticoagulans
- Von Willebrand factor
- D-dimer

Secondary outcome

- Lipid plasma levels (including cholesterol, HDL- and LDL cholesterol and triglycerides)
- The occurrence of cardiovascular events (including myocardial infarction, cerebrovascular accidents, peripheral arterial disease, arterial thrombosis) and venous thrombosis at any site

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. It is unclear whether 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 decreased levels of anticoagulant factors were found. After a year of cART, a subtle decrease in procoagulant and increase in anticoagulant factors were seen. Despite the initiation of cART therapy, the effect of persistent immune-activation and inflammation could not be ruled out, as suppression of immune activation is yet not achieved after one year of cART use. 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 in the INF-BEAST patient population after almost eight years of treatment with cART.

Study objective

The procoagulant state seen in patients with hiv can be a result of the immune activation due to the hiv infection itself or combination antiretroviral therapy (cART). In case the acquired thrombophilia is a result of immune activation, the progcoagulant state should resolve after long term (cART).

Study design

time of inclusion

Intervention

Questionnaire and blood sampling

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion in the original INF-BEAST study

Exclusion criteria

Declining informed consent to participate in the INF-BEAST2 study

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2019
Enrollment:	39
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-07-2019
Application type:	First submission

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
NTR-new	NL7884

Register	ID
Other	METC Groningen : METC2019/086

Study results