Coagulation parameters in HIV

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20034

Bron
NTR

Verkorte titel
INF-BEAST2

Aandoening

HIV, thrombophilia

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

time of inclusion

Onderzoeksproduct en/of interventie

Questionnaire and blood sampling

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion in the original INF-BEAST study

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Declining informed consent to participate in the INF-BEAST2 study

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-07-2019
Aantal proefpersonen:	39
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7884
Ander register	METC Groningen : METC2019/086

Resultaten