

The influence of antiphospholipid antibodies on INR values measured with the CoaguChek XS

Gepubliceerd: 20-04-2021 Laatste bijgewerkt: 13-12-2022

We expect differences in INR values between the CoaguChek and Coagulometer in lupus anticoagulant positive APS patients.

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

Samenvatting

ID

NL-OMON21805

Bron

NTR

Verkorte titel

APL-INR

Aandoening

Antiphospholipid syndrome, thrombosis

Ondersteuning

Primaire sponsor: Dutch Thrombosis Foundation

Overige ondersteuning: None, investigator initiated study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to determine discrepancies between INR measurements

with Coaguchek and Coagulometer in lupus anticoagulant positive APS patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Antiphospholipid syndrome (APS) is characterized by recurrent thrombosis or pregnancy complications in patients with persistent antiphospholipid antibodies. Patients with APS receive anticoagulant therapy with vitamin K antagonists (VKA) to prevent recurrent thrombosis. VKA treatment can be monitored with the international normalized ratio (INR), which is based on clotting tests. The optimal therapeutic window for VKA is an INR between 2.0 and 3.0. An INR < 2.0 is associated with an increased risk of thrombosis and an INR > 3.0 is associated with an increased risk of bleeding. Frequent monitoring and, if necessary, VKA dose adaptation, ensures patients receive adequate anticoagulation. Whilst the INR is routinely measured with clotting tests in a diagnostic laboratory, many patients monitor their own INR with Point Of Care (POC) devices. However, antiphospholipid antibodies can interfere with clotting reactions. Whereas INR reagents used in diagnostic laboratories are insensitive for interference by antiphospholipid antibodies, there are indications that reagents in POC devices are not, which could lead to false INR values and inadequate anticoagulation. In the current study, we will investigate whether INR values in APS patients measured with the most commonly used POC device in the Netherlands (CoaguChek XS) are similar to the gold standard method used in the UMC Utrecht diagnostic laboratory; the Owren method based on a rabbit brain-derived thromboplastin.

Doel van het onderzoek

We expect differences in INR values between the CoaguChek and Coagulometer in lupus anticoagulant positive APS patients.

Onderzoeksopzet

1x venepuncture and 1x finger stick per patient

Onderzoeksproduct en/of interventie

Patients will endure 1 finger stick procedure and 1 venepuncture,

Contactpersonen

Publiek

UMC Utrecht
Tessa Noordermeer

0629443806

Wetenschappelijk

UMC Utrecht
Tessa Noordermeer

0629443806

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Age 18 years and older
- Previously confirmed APS, diagnosed in accordance with the Sydney criteria²²
- Receiving VKA during at least 3 months
- Willing and be able to understand the study information and sign the informed consent form

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- None

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-05-2021
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	20-04-2021
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	NL9427

Register

Ander register

ID

METC Utrecht : 21-139

Resultaten