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

No registrations found.

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

Summary

ID

NL-OMON21805

Source
NTR

Brief title
APL-INR

Health condition

Antiphospholipid syndrome, thrombosis

Sponsors and support

Primary sponsor: Dutch Thrombosis Foundation
Source(s) of monetary or material Support: None, investigator initiated study

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to determine discrepancies between INR measurements with Coaguchek and Coagulometer in lupus anticoagulant positive APS patients.

Secondary outcome

The secondary objective of this study is to investigate which antiphospholipid antibodies correlate with the found INR discrepancies. Furthermore, we will look into the differences within two different groups of APS patients: triple positive APS patients (tested positive for at least lupus anticoagulant, anti-cardiolipin antibodies and anti-β2-glycoprotein I antibodies) and non-triple positive patients (tested positive for at least lupus anticoagulant).

Study description

Background summary

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.

Study objective

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

Study design

1x venepuncture and 1x finger stick per patient

Intervention

Patients will endure 1 finger stick procedure and 1 venepuncture,

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- None

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:	Pending
Start date (anticipated):	03-05-2021
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-04-2021
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	NL9427
Other	METC Utrecht : 21-139

Study results