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

Published: 14-04-2021
Last updated: 04-04-2024

The primary goal of this study is to determine discrepancies between INR measurements with Coaguchek XS and Coagulometer in APS patients. The secondary objective is to investigate which antiphospholipid antibodies correlate with the observed INR...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON51121

Source
ToetsingOnline

Brief title
Effect of antiphospholipid antibodies on INR values

Condition

- Autoimmune disorders
- Embolism and thrombosis

Synonym
Thrombosis in the antiphospholipid syndrome; clot formation in the antiphospholipid syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Trombosestichting Nederland

Intervention

Keyword: Antiphospholipid antibody, Antiphospholipid syndrome, International normalized ratio, Triple positive

Outcome measures

Primary outcome

The main study parameter is the difference in INR values measured with the Coaguchek XS and Coagulometer. A difference in INR >0,5 will be considered clinically significant.

Secondary outcome

Secondary parameter includes:

- The determination of antiphospholipid antibodies: IgG / IgM directed against cardiolipin, β2-Glycoprotein I, phosphatidic acid, phosphatidyl-choline, -ethanolamine, -glycerol, -inositol, -serine, annexin V and prothrombin, and antiphospholipid antibodies that prolong the clotting time in vitro, known as lupus anticoagulant. Lupus anticoagulant will be determined using a dilute Russell*s Viper Venom Time (dRVVT) screen and confirm, and an activated partial tromboplastin time (APTT) screen and confirm.

- The evaluation of differences in INR values between triple positive APS patients (patients at highest risk for recurrent thrombosis) and non-triple positive APS patients. Patients are considered as triple positive if they are tested positive for anti-cardiolipin antibodies, anti-β2GPI antibodies and lupus anticoagulant.

Study description

Background summary

Patients with the antiphospholipid syndrome (APS) often receive anticoagulant treatment with Vitamin K antagonists (VKA). Treatment with VKA is monitored with the international normalized ratio (INR), which can be determined in a diagnostic laboratory and requires a visit to an outpatient clinic, or by the patients themselves with Point Of Care (POC) devices. INR monitoring is important as low INR values indicate an increased risk of thrombosis and high INR values are associated with an increased bleeding risk. However, INR values measured with POC devices could be falsely elevated due to antiphospholipid antibodies. Previous research that have compared INR values measured with POC devices and the standard laboratory test in APS patients showed substantial methodological variantion, which makes the interpretation of the results difficult.
In the current study, we will investigate whether INR values in APS patients measured with the most commonly used POC device (CoaguChek XS) in the Netherlands are similar to INR values measured with the gold standard test, i.e. determined with the Owren method using a rabbit brain-derived thromboplastin, performed in our diagnostic laboratory at the UMC Utrecht.

Study objective

The primary goal of this study is to determine discrepancies between INR measurements with Coaguchek XS and Coagulometer in APS patients. The secondary objective is to investigate which antiphospholipid antibodies correlate with the observed INR discrepancies.

Study design

This is a monocenter, cross-sectional, observational study that will be performed in the UMC Utrecht at the van Creveldkliniek, Central Diagnostic Laboratory and the department of Rheumatology & Clinical Immunology. A total of 80 adult patients with previously confirmed APS that use Vitamin K antagonists will be included in the study. Blood withdrawal will be performed at one time moment.

Study burden and risks

For this study, patients will endure 1 finger stick procedure and 1 venepuncture (4.5 mL for study, 19 mL for biobank), which both induces a very low risk and burden to humans. The main risk associated with these procedures is little local bruising and slight local discomfort. Patients will be asked to participate during a regular outpatient clinic visit. This study has never been

performed before and will provide important information on the regulation of anticoagulant treatment in APS patients.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 18 years and older
- Previously confirmed antiphospholipid syndrome, diagnosed in accordance with the Sydney criteria
- Receiving Vitamin K antagonist during at least 3 months
- Willing and be able to understand the study information and sign the informed consent form

Exclusion criteria

- None

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):	10-06-2021
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	14-04-2021
Application type:	First submission
Review commission:	METC NedMec

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	NL76113.041.21