AntiPhosphoLipid antibodies and point-of-care INR measurement with CoaguChek - VervOlg Studie

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The primary goal of this study is to compare serial paired POC and venous INR measuremtents and to distill an individual conversion factor per patient, enabling the ungoing use of POC-INR measurement also in this patient group.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON56632

Source
ToetsingOnline

Brief title
APLIVOS

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Autoimmune disorders
- Embolism and thrombosis

Synonym
Antiphospholipid syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: onderzoeksbeurs FNT

Intervention

Keyword: Ahtiphospholipid syndrome, anticoagulation, International normalized ratio, thrombosis, Vitamin K antagonists

Outcome measures

Primary outcome

The main study parameter is the difference in INR values measured with the

Coaguchek and Coagulometer.

Secondary outcome

Secondary parameter includes the determination of antiphospholipid antibodies:

IgG / IgM directed against cardiolipin, β2-Glycoprotein I and prothrombin, and

antiphospholipid antibodies that prolong the clotting time in vitro, known as

lupus anticoagulant.

Study description

Background summary

Patients with the antiphospholipid syndrome (APS) on anticoagulant therapy can be monitored with the international normalized ratio (INR) using Point Of Care (POC) devices. However, INR values can be falsely elevated due to antiphospholipid antibodies using POC devices. Previous research from our group confirmed that POC-INR values in patients with high titers of anti-B2-glycoprotein IgG and strong lupus anticoagulant specifically give an overestimation of the true INR. At this moment, these patients are advised not to use POC-measurements any longer.
In the current study, we will compare serial INR values in APS patients measured with the most commonly used POC device (CoaguChek) in the Netherlands with whole blood INR values measured with the Owren method using a rabbit brain derived thromboplastin in our laboratory in the UMC Utrecht. We aim to distill an individual conversion factor per patient, enabling the ungoing use of POC-INR measurement also in this patient group.

Study objective

The primary goal of this study is to compare serial paired POC and venous INR measuremtents and to distill an individual conversion factor per patient, enabling the ungoing use of POC-INR measurement also in this patient group.

Study design

Prospective, single center, observational study.

Study burden and risks

For this study, patients will endure 1 finger stick procedure and 1 venapuncture (6 mL blood) at ten monthly timepoints, 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. No alterations to medication or life style are introduced.

Contacts

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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 APS, diagnosed in accordance with the Sydney criteria
- High titers of anti-B2-glycoprotein-I IgG at screening (titer > 99th percentile)
- Lupus anticoagulant positive at screening
- Receiving VKA during at least 3 months
- At least one thromboembolic event in the past
- Willing and be able to understand the study information and sign the informed consent form

Exclusion criteria

Patients with only obstetric complications of antiphospholipid syndrome without thrombotic events

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-05-2024
Enrollment:	44

Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	20-03-2024
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	05-08-2024
Application type:	Amendment
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	NL85268.041.23