Biological variation (BIOVAR) study: Performance specifications for laboratory analysis of haemostasis variables in patients with long-term treatment with Dabigatran.

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The aim of this longitudinal study is to investigate the biological variation of haemostasis variables involved in thrombosis and bleeding in patients on long-term treatment with Dabigatran. This may enable us to provide recommendations for…

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

Summary

ID

NL-OMON48347

Source
ToetsingOnline

Brief title
BIOVAR study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Cardiac arrhythmias

Synonym
atrial fibrillation, venous thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek

Intervention

Keyword: Biological variation, Dabigatran, Hemostasis

Outcome measures

Primary outcome

After this project we know the within, between and analytical individual

variation, which can be used as criteria for analyses in patients on long-term

treatment with Dabigatran.

Secondary outcome

To provide recommendations for analytical performance specifications for

laboratory tests used for the diagnosis, follow-up, and monitoring of the

treatment of thrombosis and bleeding

Study description

Background summary

Outcome of diagnostic screenings in haemostasis laboratories on blood parameters is affected by analytical or biological variation. Biological variation, within and between individuals, and analytical variation of diagnostic instruments, is now assessed using data of healthy individuals. Preferably, analytical criteria for both internal and external quality control should be based on biological variation in patients instead of healthy volunteers. Patients using the Direct Oral Anticoagulant (DOAC), Dabigatran may have a different biological variation than healthy volunteers.

Study objective

The aim of this longitudinal study is to investigate the biological variation

of haemostasis variables involved in thrombosis and bleeding in patients on long-term treatment with Dabigatran. This may enable us to provide recommendations for analytical performance specifications for laboratory tests used for the diagnosis, follow-up, and monitoring of the treatment of thrombosis and bleeding.

Study design

We intend to do a longitudinal descriptive study with repeated blood collection (in total 10 times during a 1-year period).

Study burden and risks

Patients will be asked to donate 10 ml of blood 10 times during a 1-year period. The burden will be minimized when possible, blood sample collection will be combined as much as possible with outpatient clinic visits and regular care blood drawings. As this is an observational study, there is no direct benefit for patients during the study period. However, the results of this study may benefit patients on long-term treatment with Dabigatran in diagnosis and treatment of bleeding and thrombosis. The venepuncture is the only intervention and the study does not change standard care of patients. This study gives a minimal risk for the patients* health: only complications of a venepuncture might be expected, which are minimal. DOAC*s are currently treatment of choice in patients with venous thrombosis and are used as primary and secondary prevention in patients with atrial fibrillation. To improve the diagnosis and treatment of patients on Dabigatran, it is thus needed to know the biological variation of these patients.

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

* Male and female patients, aged 18-70 years of age with atrial fibrillation or venous thrombosis.
* Patients with long-term Dabigatran use on a stable dosage for a minimum of 3 months.
* Given written informed consent.

Exclusion criteria

* Subjects with any malignancies
* Positive lupus anticoagulant.
* Body mass index (BMI)>30 kg/m2.
* Glomerular Filtration Rate (GFR) <30 ml/min.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2019
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	07-05-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL67304.078.18