New Oral Anticoagulants (NOAC) Study: Investigation of laboratory tests an development of a gold standard test for monitoring dabigatran and rivaroxaban therapy

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Choosing the most suitable laboratory test and setting up a gold standard test to measure dabigatran. Additionally, determining maximal and minimal concentrations of the drug.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON39575

Source
ToetsingOnline

Brief title
NOAC study

Condition

- Cardiac arrhythmias
- Embolism and thrombosis

Synonym
blood clot, thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: subsidie van de Nederlandse Vereniging voor Klinische Chemie

Intervention

Keyword: dabigatran, drug levels, laboratory tests, rivaroxaban

Outcome measures

Primary outcome

Several clotting tests are compared with each other and the gold standard to

select the best test.

Secondary outcome

To determine target values for dabigatran concentrations with different dosage

regimes

Study description

Background summary

New oral anticoagulant drugs have become available for several applications. Dabigatran is one of these drugs that is already used in daily practice. The pharmacokinetics and pharmacodynamics of these drugs are more predictable so that monitoring with laboratory tests seems redundant. However, this assumption is based on studies that have used extensive patient selection. More recent studies have shown that several categories of patients might need individual adaptation of dosage or monitoring, for instance in the case of extremely high or low body weight or low glomerular filtration rate. Moreover, in acute situations, for example in case of suspected overdose or acute surgery and when compliance is questioned, accurate laboratory tests will be necessary.

Study objective

Choosing the most suitable laboratory test and setting up a gold standard test to measure dabigatran. Additionally, determining maximal and minimal

concentrations of the drug.

Study design

observational study

Study burden and risks

Venipuncture for blood collection at three different time points (right before taking the next dose and 2 and 4 hours after taking the next dose), with a small risk of bruising or bleeding

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

Patients using dabigatran (CZE hospital) or rivaroxaban (MMC hospital) in a profylactic dose

Exclusion criteria

renal failure (GFR <30 ml/min), use of antiplatelet agents, previous malignancy, use of other oral anticoagulants (cumarins), age <18 years

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):	01-11-2012
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO Date:	27-12-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-08-2013
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL42009.060.12