Development and Validation of Clinical Prediction Rules for Bleeding for Patients on Anticoagulant Therapy for Venous Thromboembolism.

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General objective:To develop or validate a clinical prediction rule for major bleeding in patients on oral anticoagulant therapy (OAT) who have been safely anticoagulated without bleeding or venous thromboembolism (VTE) recurrence for 6 months since...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON57216

Source
ToetsingOnline

Brief title
Bleeding risk study.

Condition

- Embolism and thrombosis

Synonym
venous thromboembolism; deep vein thrombosis and pulmonary embolism

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anticoagulant, Bleeding risk, Clinical prediction rule, Venous Thromboembolism

Outcome measures

Primary outcome

Major bleeding as defined by the International Society of Thrombosis and Haemostasis.

Overt bleeding with at least one of the following criteria:

• associated with a fall in hemoglobin of 2g/dL or more

• leading to a transfusion of 2 or more units of packed red blood cells or whole blood

• occurring in a critical site: intracranial, intraspinal, intraocular, pericardial, intra-articular, intramuscular with compartment syndrome, retroperitoneal

• contributing to death

Secondary outcome

Clinically-relevant non-major bleeding events will also be collected. These are defined as overt bleeding episodes not meeting the inclusion for major bleeding but associated with one of the following:

• medical intervention

• an unscheduled contact with a physician

• (temporary) cessation of VKA treatment

• associated with discomfort for the patient such as pain, or impairment of

activities of daily life

Study description

Background summary

Oral anticoagulants (for example warfarin) are commonly used for the long-term treatment of venous thrombosis. Oral anticoagulants work well to prevent new thrombotic events. However, physicians and patients need to weigh the benefits of oral anticoagulant therapy (preventing new blood clots) against its potential harm (side effects such as bleeding).

Physicians are not able to predict which patients are likely to have bleeding outcomes. Much effort has gone into developing ways to predict which patient are at risk of clotting but almost no work has gone into ways of predicting which patients would be at high risk of bleeding. Investigators have previously published rules to predict major bleeding or have indicated clinical variables that suggest an increased risk of major bleeding but no rule to predict major bleeding on anticoagulants exists that can be recommended for clinical practice.
This information is required to balance off the risk-benefits and to enable physicians and patients to understand the risks and benifits of taking these medications. This study will develop a tool that can be used to predict bleeding risk in patients taking oral anticoagulant therapy. The ability to accurately predict hemorrhagic risk will enable intervention studies and have direct clinical applicability with regard to individualized decision making regarding the benefit/risk ratio of long term OAT and will result in a better control of these drugs.

Study objective

General objective:
To develop or validate a clinical prediction rule for major bleeding in patients on oral anticoagulant therapy (OAT) who have been safely anticoagulated without bleeding or venous thromboembolism (VTE) recurrence for 6 months since diagnosis and are being considered for long-term OAT.

Specific Objectives:
To determine in patients with unprovoked VTE on OAT beyond 6 months:
1) a new bleeding risk prediction rule
2) if previous rules (Beyth, van der Meer) are valid for the prediction of major bleeding
3) if variables used in previously published prediction rules are reproducible between observers

4) the factors that influence OAT control
5) the degree to which being over the therapeutic INR range influences major bleeding, independent of OAT control.

Study design

Observational, prospective multicenter cohort study.

Study burden and risks

Enrollment: A visit is planned for blood sampling and the patient will be asked about things that might affect the dose of oral anticoagulant or risk of bleeding (e.g. age, current or past health problems, medications).

After the enrollment, a half yearly follow-up is planned, this will be done by an interview by telephone. Patients will be asked questions about bleeding and the signs and symptoms of a new thrombotic event. There will also be questions about changes in health situation and medications.

This is an observational study so there are no risks involved. Participating in the study will not change the risk of a new thrombotic event 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

- At least 18 years old
- Unprovoked venous thromboembolism
- Objectively comfirmed venous thromboembolism
- Treated with an oral anticoagulant for 5-8 months with plans to continue (vitamin K antagonist or new oral anticoagulant)
- If taking a vitamin K antagonist; INR target is between 2.0-3.0
- If taking a vitamin K antagonist; must have taken it for the last 3 consecutive weeks (minuimum)

Exclusion criteria

- Recurrent venous thromboembolism during the 5-8 month treatment period prior to study enrolment
- Major bleeding event during the 5-8 month treatment period prior to study enrolment
- Cancer diagnosis during the 5-8 month treatment period prior to study enrolment
- Unable to provide written informed consent
- Refusal to provide written informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	60
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	26-06-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL26900.058.09
Other	NTC00788736

Study results

Date completed:	14-04-2014

Summary results
Trial never started