Leiden Thrombosis Recurrence Risk Prevention

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To determine which patients, individually classified for VTE ánd bleeding risk, will benefit from prolonged anticoagulant treatment without being unnecessarily exposed to its risks.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Embolism and thrombosis
Study type	Interventional

Summary

ID

NL-OMON26314

Source
NTR

Brief title
L-TRRiP study

Condition

- Embolism and thrombosis

Synonym
VTE

Health condition

Venous thromboembolism (deep vein thrombosis and pulmonary embolism)

Research involving
Human

Sponsors and support

Primary sponsor: Leiden University Medical Centre
Source(s) of monetary or material Support: ZonMw (grant number 848017007)

Intervention

Outcome measures

Primary outcome
Combination of recurrent VTE and major bleeding (defined according to ISTH criteria) in the randomised group

Secondary outcome

- Combined endpint weighted for quality of life and functional status (measured by EQ-5D and PVFS)
- Recurrent VTE and bleeding in non-randomised groups
- Clinically relevant non-major bleeding
- Cost-effectiveness (measured by the iMTA MCQ and iMTA PCQ questionnaires)
- Functional recovery (measured by post-vte functional status scale)

Study description

Background summary

Patients with a first venous thromboembolism (VTE) have a high risk of recurrence. Anticoagulant therapy is effective for prevention but not suitable for long-term treatment of all patients due to its bleeding risk. Currently, it is unclear which patients will benefit most from prolonged treatment and for whom such treatment is redundant. Hence, many patients are over- or undertreated for a prolonged period.

Study objective

To determine which patients, individually classified for VTE ánd bleeding risk, will benefit from prolonged anticoagulant treatment without being unnecessarily exposed to its risks.

Study design

"Study design: A cohort-based, randomised, controlled, open trial with blinded endpoint assessment and at least 2 years follow-up. Study population: Patients without cancer, treated with anticoagulants for a first VTE who are about to complete this treatment. Intervention: Individual estimation of recurrent VTE (low, intermediate or high) and major bleeding risk (low or high) and treatment decision based on these risks. Randomisation to continuation or discontinuation of anticoagulation in a subgroup of patients (i.e. patients with intermediate recurrence risk, or high recurrence risk and high bleeding risk). Sample size: 608 patients in randomised group, total cohort size depending on the distribution of randomised and non-randomised patients. Main study parameters/endpoints: The primary outcome will be the combination of recurrent VTE and major bleeding events. Secondary outcomes are 1) the

combined endpoint with both events weighted by the associated quality-adjusted life year (QALY) loss and 2) cost-effectiveness."

Intervention

Individual estimation of risks and benefits of continuation of anticoagulant treatment and treatment decision based on these risks. Randomisation to continuation or discontinuation of anticoagulation in a subgroup of patients.

Study burden and risks

For patients, participation in this study will have as a small extra burden compared with the current policy that short questionnaires need to be filled in throughout the study duration and that a buccal swab will need to be taken at the start of the study. However, no extra visits to the clinic are necessary, nor is extra blood sampling, and the detailed risk assessment and according treatment may benefit their health outcomes.

Contacts

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Eligibility criteria

Age

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

Elderly (65 years and older)

Inclusion criteria

1. Provision of informed consent prior to any study specific procedures.
2. Be diagnosed with a first confirmed symptomatic deep vein thrombosis (including distal vein thrombosis, in Dutch: 'kuitvenetrombose') of the lower extremity or pulmonary embolism with an indication for treatment with anticoagulant therapy for at least 3 months as prescribed by their treating physician.
3. Be aged 18 years or above.

Exclusion criteria

1. Patients with active cancer (i.e. cancer diagnosis within six months before VTE (excluding basal-cell or squamous-cell carcinoma of the skin), recently recurrent or progressive cancer or any cancer that required anti-cancer treatment within six months before the venous thromboembolism was diagnosed) or antiphospholipid syndrome.
2. Patients who need to continue anticoagulant treatment for another indication (e.g. atrial fibrillation).
3. Patients with a strong indication for long-term antiplatelet therapy despite oral anticoagulation (e.g. those with recent STEMI).
4. Patients with COVID-19 associated VTE (i.e. hospital admission because of COVID-19 <3 months before the VTE) or vaccine induced immune thrombotic thrombocytopenia (VITT).
5. Patients in whom the risk of bleeding is deemed extremely high by the treating physician, necessitating discontinuation of anticoagulant treatment for the first VTE after the initial 3 months or even during the initial 3 months.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-06-2021
Enrollment:	608
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	05-02-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 54327
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9003
Other	METC Leiden Den Haag Delft : P20.090, NL74711.058.20

Register	ID
CCMO	NL74711.058.20
OMON	NL-OMON54327

Study results