Leiden Thrombosis Recurrence Risk Prevention: Tailored treatment after a first venous thromboembolism: (L-TRRiP study)

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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-OMON54327

Source
ToetsingOnline

Brief title
L-TRRiP study

Condition

- Embolism and thrombosis

Synonym
'Venous thromboembolism' 'thrombosis'

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw (GGG subsidie)

Intervention

Keyword: Prevention, Treatment duration, Trial, Venous Thromboembolism

Outcome measures

Primary outcome

The primary outcome will be the combination of recurrent VTE and major bleeding events.

Secondary outcome

Secondary outcomes are 1) the combined endpoint (recurrent VTE and major bleeding) with both events weighted by the associated quality-adjusted life year (QALY) loss and 2) cost-effectiveness.

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

A cohort-based, randomised, controlled, open trial with blinded endpoint assessment and at least 2 years follow-up.

Intervention

Individual estimation of risks and benefits of continuation of treatment based on the VTE-BLEED and L-TRRiP model; and treatment decision based on these risks. Discontinuation of anticoagulation for those with a low risk of recurrent thrombosis, continuation of anticoagulation for those with a high risk of reccurent thrombosis and low risk of major bleeding, randomisation to continuation or discontinuation of anticoagulation in the other 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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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
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') 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 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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-06-2021
Enrollment:	1600
Type:	Actual

Ethics review

Approved WMO Date:	05-02-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	22-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	18-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	21-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	28-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	06-01-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	23-10-2023

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	06-09-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	27-01-2025
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (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

ID: 26314
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74711.058.20
Other	NL9003