Prediction of cancer-associated venous thromboembolism

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23071

Source
NTR

Brief title
EVENT

Health condition

Cancer-associated venous thromboembolism

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Tergooi Hospitals

Intervention

Outcome measures

Primary outcome

- Venous thromboembolism in the 6 months following cancer diagnosis

Secondary outcome

- Venous thromboembolism in 12 months and longer follow-up periods after cancer diagnosis.

- Venous thromboembolism in the 6 months, 12 months and longer follow-up periods after reactivation of cancer.
- Arterial thromboembolism in 6 months, 12 months and longer follow-up periods after primary cancer diagnosis or reactivation of cancer.
- Mortality in 6 months, 12 months, and longer follow-up periods after primary cancer diagnosis.

Study description

Background summary

Venous thromboembolism (VTE) is a common complication in patients with cancer, leading to increased mortality and morbidity, decreased quality of life and higher healthcare costs. Primary thromboprophylaxis with low molecular weight heparin (LMWH) has been shown to be efficacious in preventing VTE, reducing the risk with 46%. However, current international guidelines do not recommend routine prophylactic anticoagulant therapy in ambulatory cancer patients due to an unfavorable risk-benefit ratio. Risk stratification tools using clinical and laboratory variables have been developed to help predict which patients will develop cancer-associated VTE. However, external validation of these tools remain needed before clinical implementation can be justified. The main objective of this study is to evaluate and compare the performance several risk scores, including the Khorana, PROTECHT and CONKO and TIC-ONCO score. In addition, the additive value of other clinical risk factors and genetic mutations will be evaluated.
We aim to enroll all CPCT-02 study (clinicaltrials.gov identifier: NCT01855477) participants in a retrospective cohort study. Enrollment of at least thousand patients is intended in order to observe around 50-80 events to provide sufficient statistical power.

Study objective

VTE risk prediction might be improved by using the modified risk scores.

Study design

6 months from entry time, 12 months from entry time, and longer follow-up periods.

Contacts

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Eligibility criteria

Inclusion criteria

- Adult patients (age >18 years)
- Ambulatory setting
- Histologically or cytologically confirmed cancer
- Chemotherapy indicated within 3 months

Exclusion criteria

- Desmoid tumors
- Pre-stages of cancer

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2019

Enrollment:	2000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
As data is owned by a third party, sharing of patient-level data is not possible.

Ethics review

Positive opinion

Date:	09-09-2019
Application type:	First submission

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
NTR-new	NL8010
Other	The study has been declared not to be subject to the Medical Research Involving Human Subject Act (WMO). The study was approved by the Independent Review Board (IRB) in hospitals were this was required. : MEC-2018-1468

Study results