Prediction of cancer-associated venous thromboembolism

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23071

Bron
NTR

Verkorte titel
EVENT

Aandoening

Cancer-associated venous thromboembolism

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Tergooi Hospitals

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Venous thromboembolism in the 6 months following cancer diagnosis

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Desmoid tumors
- Pre-stages of cancer

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-06-2019
Aantal proefpersonen:	2000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

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

Ethische beoordeling

Positief advies

Datum:	09-09-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8010
Ander register	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

Resultaten