Predicting venous thromboembolism with the FGT test in patients with pancreatic cancer

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The improved fibrin generation test, and other biomarkers are predictive for venous thromboembolism in cancer patients

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

Samenvatting

ID

NL-OMON19867

Bron
Nationaal Trial Register

Verkorte titel
SENECA

Aandoening

Venous thromboembolism, arterial thromboembolism

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Amsterdam UMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The purpose of current study is to evaluate the predictive performance of the improved FGT

for the development of VTE in pancreatic cancer patients. The primary outcome is VTE occurring within 6 months from enrolment, including any symptomatic proximal and distal DVT of the upper or lower limbs, any non-fatal symptomatic or incidental segmental of more proximal PE, VTE-related deaths (fatal PE or unexplained death), as well as all other sites of VTE (distal upper & lower DVT, cerebral vein, splenic vein, renal vein, gonadal vein). Catheter related venous thromboembolism will not be considered as the primary outcome. The diagnosis needs to be confirmed by an independent radiologist by means of ultrasonography or computed tomography. No routine radiologic imaging will be performed for this study.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Venous thromboembolism is a relevant complication in cancer patients as it is associated with substantial morbidity, can lead to cancer treatment interruption, and is the second cause of death after cancer progression itself. Patients with pancreatic cancer are at very high risk of developing venous thromboembolism, which is thought to be due to the release of extracellular vesicles that carry tissue factor by tumor cells. The fibrin generation test aims to measure the coagulant activity associated with these tissue factor carrying extracellular vesicles. The test was recently improved and could be a valuable tool for predicting venous thromboembolism.
Objective: The main objective is to assess the reproducibility of the improved fibrin generation test and its value in predicting venous thromboembolism in pancreatic cancer patients. Secondary objectives are to assess the predictive value of several other potentially predictive (bio)markers.

Doel van het onderzoek

The improved fibrin generation test, and other biomarkers are predictive for venous thromboembolism in cancer patients

Onderzoeksopzet

Baseline and 6 months follow-up

Contactpersonen

Publiek

Amsterdam UMC
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Adenocarcinoma of the pancreas confirmed by histology or radiologic imaging.
• Planned for a new course of chemotherapy
• 18 years of age or older
• Fully capable of making health related decisions and written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Adjuvant chemotherapy.
• Current prophylactic or therapeutic anticoagulant therapy (unfractionated heparin, low molecular weight heparin, vitamin K antagonists, or direct oral anticoagulants).
• Venous thromboembolism < 3 months prior to chemotherapy.
• Surgery within the last month
• Start of chemotherapy before enrolment
• The presence of an inferior vena cava filter
• Currently pregnant
• Life expectancy of <3 months
• Bacterial or viral infection in the previous 2 weeks, defined by fever and clinical symptoms.
• Chemotherapy in the last month

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:	02-01-2019
Aantal proefpersonen:	112
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Not decided yet

Ethische beoordeling

Positief advies

Datum:	12-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52393
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7660
CCMO	NL66531.018.18
OMON	NL-OMON52393

Resultaten