ONCOR: Dutch cardio-oncology registry

Gepubliceerd: 03-10-2019 Laatst bijgewerkt: 18-08-2022

Observational longitudinal cohort to investigate the incidence of cancer treatment-related cardiovascular toxicity, identification of risk factors and evaluation of treatment strategies.

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

Samenvatting

ID

NL-OMON25455

Bron
Nationaal Trial Register

Verkorte titel
ONCOR

Aandoening

Patients who will be-, are-, or have been treated with potential cardiotoxic oncological treatment and therefore a referred to specialized cardio-oncology units.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: University Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cardiovascular toxicity

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The attention for cardiovascular side effects of anticancer treatment has grown and led to increased knowledge of pathophysiological mechanisms, diagnostics- and treatment of these feared side effects. Despite these advantages, there are still several unresolved issues and challenges within the field of cardio-oncology such as absence of a validated risk stratification model and optimal treatment for cancer therapy-related cardiac dysfunction. ONCOR is a prospective multicenter registry in which clinical information of patients visiting cardio-oncology units across the Netherlands will be collected. The primary objective is to register the incidence of cardiovascular toxicity of cancer treatment. Secondary objectives include the influence of cardiovascular toxicity on oncological treatment, identification of risk factors for cardiotoxicity. Additionally, the registry provides a platform for future (interventional) studies, including registry-based randomized clinical trials.
Objective: Incidence of cardiovascular toxicity of cancer treatment; Identification of risk factors for the development of cardiovascular toxicity.
Study design: Prospective multicenter observational cohort study
Study population: Patients receiving cardio-oncological care in Dutch hospitals.
Intervention: No intervention will take place. Patients are treated according to routine clinical practice.
Main study parameters/endpoints: The occurrence of cardiovascular toxicity and impact on oncological treatment. Identifying risk factors for development of cardiovascular toxicity.
Determinants: Registration of oncological treatment and the occurrence of cardiovascular side effects.
Nature and extent of the burden and risk associated with participation, benefit and group relatedness: Participation in the registry will not give extra burden or risk for the patients. It will not provide direct benefit for the patient.

Doel van het onderzoek

Observational longitudinal cohort to investigate the incidence of cancer treatment-related cardiovascular toxicity, identification of risk factors and evaluation of treatment strategies.

Onderzoeksopzet

Visits at the cardio-oncology unit will be registered.

Onderzoeksproduct en/of interventie

No intervention will take place. Patients are treated according to routine clinical practice.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients who visit a specialized cardio-oncology unit.
- Age ≥18 years.
- Willing and able to provide written informed consent for participation

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Conditions that affect a patient’s ability to provide written informed consent, such as psychiatric or mental disorders, language barriers or other factors

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:	01-03-2019
Aantal proefpersonen:	2000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-10-2019
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	NL8064
Ander register	METC UMCU : METC 18/639

Resultaten