ONCOR: Dutch cardio-oncology registry

No registrations found.

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

Summary

ID

NL-OMON25455

Source
Nationaal Trial Register

Brief title
ONCOR

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

Cardiovascular toxicity

Secondary outcome

Changes in oncological treatment due to cardiovascular toxicity; Major Adverse Cardiovascular Events; All-cause mortality;

Study description

Background summary

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.

Study objective

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

Study design

Visits at the cardio-oncology unit will be registered.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

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):	01-03-2019
Enrollment:	2000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-10-2019
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	NL8064
Other	METC UMCU : METC 18/639

Study results