

Markers for Acute Chemotherapy-Induced Cardiovascular Changes

Submission date 19/07/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/07/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/07/2006	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym
MACC1

Study objectives

1. The number of circulating endothelial (progenitor) cells may be reduced during chemotherapy and correlate to the development of cardiovascular disease
2. Oxidative stress due to chemotherapy may lead to an increased accumulation of advanced glycation end products (AGEs) in blood vessels, contributing to endothelial damage

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

An observational study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Testicular cancer

Interventions

The number of circulating endothelial cells, endothelial marker proteins and accumulation of AGEs (estimated by measuring skin autofluorescence with an AGE-reader) will be determined before, during and after chemotherapy.

Cardiovascular status (intima-media thickness of the carotid artery, baroreflex sensitivity and 24-hour ambulatory blood pressure measurement) will be evaluated before start of chemotherapy, within four weeks after completion of chemotherapy and one year after start of chemotherapy.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cisplatin

Primary outcome(s)

The early effects of cisplatin-based chemotherapy on the number of circulating endothelial (progenitor) cells and the accumulation of AGEs, and their correlation with cardiovascular damage

Key secondary outcome(s)

1. Evaluation of which treatment and patient-related factors (for example chemotherapy dose and presence of cardiovascular risk factors) predispose patients to cardiovascular damage during and after cisplatin-based chemotherapy

2. Determination of circulating apoptosis markers during and after cisplatin-based chemotherapy and their relation to tumor response and cardiovascular damage

Completion date

01/05/2009

Eligibility

Key inclusion criteria

1. Patients with disseminated testicular cancer who will be treated with cisplatin based chemotherapy
2. Age 18-50 years at start of treatment
3. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

Male

Key exclusion criteria

1. Medical history of cardiovascular disease
2. Known renal disease or estimated glomerular filtration rate (GFR) <60 ml/min (using Cockcroft-Gault formula)

Date of first enrolment

16/05/2006

Date of final enrolment

01/05/2009

Locations

Countries of recruitment

Netherlands

Study participating centre
Medische Oncologie
Groningen
Netherlands
9713 GZ

Sponsor information

Organisation

University Medical Center Groningen (UMCG), Department of Internal Medicine: Division of Medical Oncology (The Netherlands)

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

University/education

Funder Name

University Medical Center Groningen (UMCG)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration