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Markers for Acute Chemotherapy-Induced Cardiovascular Changes

Submission date 19/07/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/07/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/07/2006	**Condition category** Cancer	[_] Individual participant data [_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
16/05/2006

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Male

Target number of participants

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)

Sponsor details
P.O. Box 30001
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Sponsor type
University/education

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
University/education

Funder Name
University Medical Center Groningen (UMCG)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration