

# Markers for Acute Chemotherapy-Induced Cardiovascular Changes

<b>Submission date</b> 19/07/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/07/2006	<b>Condition category</b> 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

**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