Changes to the mitochondrial DNA in non-cancer cells induced by chemotherapy and the relation with fatigue in men with germ-cell cancer of the testis: a feasibility study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON45432

Source
ToetsingOnline

Brief title
Mitochondrial DNA and fatigue.

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Fatigue in men with testicular cancer

Research involving
Human

Sponsors and support

Primary sponsor: Interne Oncologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chemotherapy, Fatigue, Mitochondrial DNA

Outcome measures

Primary outcome

A decrease >=30% in the number of mtDNA molecules per cell AND/OR an increase of >=11 damage lesion per 10 kb in mtDNA of blood cells during chemotherapy (measurements 2 and 3) and three months after completing chemotherapy (measurement 4), compared to baseline (measurement 1).

Secondary outcome

The severity of physical fatigue and mental fatigue at baseline (measurement 1), during chemotherapy (measurement 2 and 3), and three months after completing chemotherapy (measurement 4).

Mitochondrial functioning in blood cells at baseline (measurement 1), during chemotherapy (measurement 2 and 3), and three months after completing chemotherapy (measurement 4).

Study description

Background summary

Cancer-related fatigue is experienced in all stages of the disease trajectory. Despite much research, the pathogenesis of fatigue is still unknown. Cancer patients indicate that fatigue is more troublesome and has a greater negative influence on quality of life and daily activities than any other cancer-related symptom, including pain, nausea and depression.

One of the working mechanism of chemotherapeutic regimen is severe damage to the nuclear genome of the tumor cell to impair cell division. Studies indicate that chemotherapy does not only damage the nuclear genome, but also affects the mitochondrial DNA. Mitochondria, small organelles found in eukaryotic cells, are responsible for the energy production of the cell by the respiratory chain. Mitochondrial DNA is responsible for the production of 13 polypeptides involved in the respiratory chain. The consequence of changes in mitochondrial DNA is illustrated by mitochondrial myopathies with symptoms including experiences of fatigue.

Because cancer patients undergoing chemotherapy can become fatigued and chemotherapy might induce mitochondrial impairment via changes in mitochondrial DNA, it could be hypothesized that cancer-related fatigue is due to functional impairment of mitochondria caused by chemotherapy. Therefore, we want to perform a feasibility study in a small but homogeneous group of cancer patients treated with chemotherapy. We aim to include men with metastatic germ cell cancer of the testis, planned to be treated with chemotherapy. These relatively young patients become severely fatigued during chemotherapy and the prevalence of chronic fatigue ten years after completing treatment in this population is almost twice as high as in the general population.

Study objective

In this pilot study, we want to investigate whether it is feasible to study the accumulation of changes in mtDNA in non-cancer cells as a possible explanation for the development of fatigue in patients treated with chemotherapy for metastatic testicular cancer.

Study design

We aim to conduct an observational study with four measurement points:
1) Before the administration of the first cycle chemotherapy
2) Before the administration of the second cycle chemotherapy
3) Before the administration of the third cycle chemotherapy
4) At the second follow-up visit after completing chemotherapy (±14 weeks)

Study burden and risks

Limited burden: Blood sampling is part of the regular care and thus no additional invasive investigation.
Limited risk: Blood sampling is part of the regular care.

Contacts

Public
Selecteer

High Tech Campus 11
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NL
Scientific
Selecteer

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Eindhoven 5656 AE
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Men with metastatic germ cell cancer of the testis planned to receive three cycles of BEP chemotherapy (bleomycin, etoposide, cisplatin)
-Signed informed consent

Exclusion criteria

-Received chemotherapy before
-Chronic Fatigue Syndrome or fibromyalgia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2017
Enrollment:	37
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-01-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22518
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58942.078.16
OMON	NL-OMON22518