Mitochondrial DNA and fatigue

No registrations found.

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

Summary

ID

NL-OMON22518

Source
NTR

Brief title
FIESTA

Health condition

Testicular germ-cell cancer, cancer-related fatigue, mitochondrial DNA, bleomycin, etoposide, cisplatin, BEP-chemotherapy

Testiscarcinoom, kanker gerelateerde vermoeidheid, mitochondriaal DNA, bleomycine, etoposide, cisplatine, BEP-chemotherapie

Sponsors and support

Primary sponsor: Erasmus MC Cancer Institute, department of Medical Oncology
Source(s) of monetary or material Support: Erasmus MC Cancer Institute, department of Medical Oncology

Intervention

Outcome measures

Primary outcome

To determine whether chemotherapy for metastatic germ cell cancer of the testis (bleomycin/etoposide/cisplatin) induces changes in mtDNA of non-cancer cells that persist

after completion of chemotherapy. This will give indirect information on possible impairment of mitochondrial functioning.

Secondary outcome

- To determine whether persistent mitochondrial impairment is observed in these non-cancer cells.

- To determine the severity of fatigue before, during and after the chemotherapy cycles and its relation with the occurrence of changes in mtDNA in non-cancer cells.

Study description

Background summary

Fatigue is a problem frequently experienced by cancer patients. Unfortunately, the pathogenesis of fatigue is still unknown. A few studies show that the administration of chemotherapy is associated with changes in the DNA of mitochondria (mtDNA), small organelles responsible for the energy production of the cell. However, whether chemotherapy changes mtDNA in healthy cells and which consequences that may bear have not been investigated. We hypothesize that chemotherapy for metastatic germ cell cancer of the testis induces mitochondrial impairment and/or off-target changes in mitochondrial DNA of healthy cells which possibly persists after completion of chemotherapy regimen. If so, this might contribute to the elucidation of the pathophysiology of cancer-related fatigue.

Study objective

We hypothesize that changes in mitochondrial DNA and functional mitochondrial defects are detectable in blood cells during and after treatment with BEP-chemotherapy.

Study design

- Before the administration of the first cycle chemotherapy

- Before the administration of the second cycle chemotherapy

- Before the administration of the third cycle chemotherapy

- At the second follow-up visit after completing chemotherapy (±14 weeks)

Intervention

Blood draw (10mL of blood) for collection of peripheral white blood cells to study

mitochondrial functioning and DNA quality before the administration of each BEP cycle (3x) and at follow-up (1x).

Contacts

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Eligibility criteria

Inclusion criteria

- Planned to receive three cycles of chemotherapy (bleomycin, etoposide, cisplatin) for metastatic testicular cancer

- Age of 18 years or older

- Able to write and speak Dutch

- Provide informed consent

Exclusion criteria

- Cognitive impairments (i.e. inability to understand patient information leaflet or fatigue questionnaires)

- Chronic Fatigue Syndrome or fibromyalgia

- Received chemotherapy before

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):	24-02-2017
Enrollment:	37
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-07-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45432
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7180
NTR-old	NTR7372
CCMO	NL58942.078.16
OMON	NL-OMON45432

Study results