Mitochondrial DNA and fatigue

Gepubliceerd: 18-07-2018 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22518

Bron
NTR

Verkorte titel
FIESTA

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC Cancer Institute, department of Medical Oncology
Overige ondersteuning: Erasmus MC Cancer Institute, department of Medical Oncology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

- 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)

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

- Chronic Fatigue Syndrome or fibromyalgia

- Received chemotherapy before

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-02-2017
Aantal proefpersonen:	37
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45432
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten