Pilot studie: Dystrofische signaalpaden in haarfollikels na chemotherapie

Gepubliceerd: 06-01-2014 Laatst bijgewerkt: 15-05-2024

Damage response pathways can possibly explain the working mechanism of scalp cooling

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

Samenvatting

ID

NL-OMON22244

Bron
Nationaal Trial Register

Verkorte titel
PATH study

Aandoening

Signaalpad, kaalheid, chemotherapie, hoofdhuidkoeling
Pathway, alopecia, chemotherapy, scalp cooling

Ondersteuning

Primaire sponsor: Medisch Centrum Alkmaar
Overige ondersteuning: Medisch Centrum Alkmaar

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Expression of damage-response pathways

Toelichting onderzoek

Achtergrond van het onderzoek

Alopecia is an almost inevitable side effect of chemotherapy treatment. In cancer patients chemotherapy induced alopecia
is experienced as one of the side effects with de most impact. Several factors may contribute to the severity of hair loss
including dose, drug schedule, combinations with other cytotoxic agents as well as hair care practices. Research shows
scalp cooling is an effective method to prevent chemotherapy induced hair loss. The exact working mechanism is unclear.
Therefore we do not know why scalp cooling is effective in one patient but not in another.

The objective of this study is to explore molecular damage-response pathways such as p53 expression in hair follicles
after chemotherapy.

The study will be conducted in the outpatient chemotherapy clinic of the
department of internal medicine of the Medical Center Alkmaar. Patients will be asked to participate at the time of their first
contact with the oncology nurse to schedule their first chemotherapy. After providing informed consent, hairs will be
collected during the first chemotherapy course.

Doel van het onderzoek

Damage response pathways can possibly explain the working mechanism of scalp cooling

Onderzoeksopzet

Hair samples will be collected at different time points.

Hair samples will be collected at:

t=0 (before treatment with chemotherapy)

t=2 (two days after chemotherapy)

t=4 (four days after chemotherapy)

t=8 (eight days after chemotheray)

t=12 (twelve days after chemotherapy)

t=16 (sixteen days after chemotherapy)

The study will end when no fluctuation is seen between the different time-points.

Onderzoeksproduct en/of interventie

This pilot study will explore molecular damage-response pathways such as p53 expression in hair follicles after chemotherapy. It is known that all patients treated wit TAC, FEC and AC (any combination chemotherapy schedule including an anthracycline) lose their hair within two to three weeks. This pilot study explores various time-points to detect whether p53 fluctuates between these time-point. If there is no fluctuation between the different time-points in ten patients, it is unlikely to detect any fluctuation when more patients are included.

Contactpersonen

Publiek

Wilhelminalaan 12
M.M.C. Komen
Alkmaar 1815 JD
The Netherlands
+31 (0)72 5482872

Wetenschappelijk

Wilhelminalaan 12
M.M.C. Komen
Alkmaar 1815 JD
The Netherlands
+31 (0)72 5482872

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Female patients with breast cancer

- Age 18 years or more

- Written informed consent

- Indication for at leaust one cycle of intravenous administered Docetaxel-Adriamycin-Cyclofosfamide (TAC),
Fluorouracil-Epirubicin-Cyclophosphamide (FEC) or Adriamycin-Cyclophosphamide (AC).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Use of scalp cooling

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2013
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40394
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4192
NTR-old	NTR4343
CCMO	NL45436.094.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40394

Resultaten

Samenvatting resultaten
N/A