

Dystrophic pathways in human hair follicles after chemotherapy with or without scalp cooling

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

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

Samenvatting

ID

NL-OMON27897

Bron

NTR

Verkorte titel

PATH-2

Aandoening

Chemotherapy, Scalp Cooling, Alopecia, Dystrophic Pathway, Hair follicle

Chemotherapie, hoofdhuidkoeling, alopecia, dystrofisch signaalpad, haar follikel

Ondersteuning

Primaire sponsor: Noordwest Ziekenhuisgroep

Overige ondersteuning: Noordwest Ziekenhuisgroep

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Chemotherapy acts on rapidly growing cells, including hair follicles. Chemotherapy-induced shedding of hairs usually occurs 7–14 days after infusion. For patients, chemotherapy-induced alopecia (CIA) is one of the most distressing side-effects of treatment. Scalp cooling can prevent or minimise CIA. The rationale for the use of scalp hypothermia has not been completely elucidated and may depend on p53, Caspase-3 and Bax/bcl2. Suppression of these enzymes is possibly one of the underlying mechanisms influencing the effect of scalp cooling.

The objective of this study is to determine the dystrophic pathway factors involved in chemotherapy induced-apoptosis (programmed cell death) in the hair follicle after chemotherapy.

The study will be conducted in the out-patient chemotherapy clinic of the department of Internal Medicine of the Northwest Clinics.

Study population: The study will enroll ten patients with breast cancer (with/ without scalp cooling) evaluable for one cycle of intravenous administered taxane containing chemotherapy.

Doel van het onderzoek

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

Onderzoeksopzet

Hairs will be collected at six different time points T=0 acts as a control time point as no chemotherapy is administered.

Hair sample collection time points:

t=0 (before treatment with chemotherapy)

t=1 (one day after chemotherapy)

t=2 (two days after chemotherapy)

t=3 (three days after chemotherapy)

t=5 (five days after chemotherapy)

t=7 (seven days after chemotherapy)

Onderzoeksproduct en/of interventie

Why scalp cooling is effective in one patient but not in another remains unclear. As the rationale for the use of scalp hypothermia has not been completely elucidated, the cooling protocol may not be optimal. To understand the underlying pathobiology of CIA, we investigate molecular damage-response pathways in hair follicles after chemotherapy and the influence of scalp cooling on these molecular pathways.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients with cancer
- Indication for at least one cycle docetaxel or paclitaxel

- Age 18 years or more
- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Not applicable

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	16-03-2017
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	03-11-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6057
NTR-old	NTR6204
Ander register	METC Noord-Holland : M016-044

Resultaten

Samenvatting resultaten

NA