Mechanisms of Scalp Cooling During Chemotherapy

Gepubliceerd: 01-09-2011 Laatst bijgewerkt: 18-08-2022

Skin temperature can possibly affect the effect of scalp cooling. The primary objective is to search for the possible relation between hair loss and the obtained scalp skin temperature with scalp cooling at a standard temperature.

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

Samenvatting

ID

NL-OMON26586

Bron
NTR

Verkorte titel
MOSCOU

Aandoening

Temperature, Scalp Cooling, Alopecia, Chemotherapy

Ondersteuning

Primaire sponsor: Medisch Centrum Alkmaar
Overige ondersteuning: Foreest Institute Alkmaar, Medisch Centrum Alkmaar

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Hair loss will be the primary outcome variable. Hair loss will be measured asking the patient whether or not a wig or head cover is required, using the World Health Organisation (WHO)

grading system and a visual analogue scale (VAS), making pictures and using a trichometer (a diagnostic instrument for measuring changes in hair quantity (mass, hair diameter and hair density).

Toelichting onderzoek

Achtergrond van het onderzoek

In cancer patients chemotherapy-induced alopecia remains one of the most frequently encountered side-effects of treatment. Scalp cooling is often an effective method to prevent chemotherapy-induced hair loss. Skin temperature, skin perfusion, drug exposure and scalp cooling time may contribute and have to be taken into account in improving the protocol for scalp cooling during administration of chemotherapy.

The primary objective of this study is to search for the possible relation between hair loss and the obtained scalp skin temperature with cooling at a standard temperature. A secondary objective is to identify a temperature cut-off score under which alopecia can be prevented by scalp cooling.

Doel van het onderzoek

Skin temperature can possibly affect the effect of scalp cooling. The primary objective is to search for the possible relation between hair loss and the obtained scalp skin temperature with scalp cooling at a standard temperature.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with breast cancer;

2. Age 18 years or more;

3. Written informed consent;

4. Indication for three to six cycles of intravenous administered 5-Fluorouracil-Epirubicin-Cyclophosphamide (FEC) regimen with an epirubicine dose of 90-100 mg/m2 at 3-weekly intervals or Adriamycin-Cyclophosphamide (AC) (adryamycin at a dose of 60 mg/m2;

5. Subsequent chemotherapy consisting of decetaxel or paclitaxel is allowed after three cycles of FEC or AC.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Clinical signs of scalp metastases;

2. Cold sensitivity;

3. Cold agglutinin disease;

4. Cryoglobulinemia;

5. Cryofibrinogenemia;

6. Cold posttraumatic dystrophy.

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:	01-05-2011
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	01-09-2011
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	NL2935
NTR-old	NTR3082
Ander register	METC Noord-Holland : M011-013
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A