Mechanisms of Scalp Cooling During Chemotherapy

No registrations found.

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

Summary

ID

NL-OMON26586

Source
NTR

Brief title
MOSCOU

Health condition

Temperature, Scalp Cooling, Alopecia, Chemotherapy

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Foreest Institute Alkmaar, Medisch Centrum Alkmaar

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

N/A

Contacts

Public
Wilhelminalaan 12
M.M.C. Komen
Alkmaar 1815 JD

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

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Clinical signs of scalp metastases;

2. Cold sensitivity;

3. Cold agglutinin disease;

4. Cryoglobulinemia;

5. Cryofibrinogenemia;

6. Cold posttraumatic dystrophy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2011
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	01-09-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2935
NTR-old	NTR3082
Other	METC Noord-Holland : M011-013
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A