A study of scalp skin temperature during scalp cooling in patients treated with chemotherapy.

No registrations found.

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

Summary

ID

NL-OMON23651

Source
NTR

Brief title
FECTemp

Health condition

Scalp cooling, alopecia, temperature, FEC chemotherapy

Hoofdhuidkoeling, haaruitval, temperatuur, FEC chemotherapie

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The pilot study will check the feasibility of the main study, after which specific parameters/outcomes will be defined. 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 the trichometer (a diagnostic instrument for measuring changes in hair quantity (mass), hair diameter, and hair density).

Secondary outcome

N/A

Study description

Background summary

The primary aim of this study is to assess variations in scalp skin temperature between patients during scalp cooling in the high dose FEC-regimen, thereby improving the results of scalp cooling in the high dose 5Fluorouracil-Epirubicin-Cyclophosphamide (FEC) regimen.

Study objective

Skin temperature can possibly affect the effect of scalp cooling. First a pilot study will be conducted to check the feasibility of the main study. The primary objective of the main study is to identify a cut-off score under which alopecia can be prevented by scalp cooling.

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 mg/m2 or more at 3-weekly intervals.

Exclusion criteria

1. Boldness before the start of the study;

2. Clinical signs of scalp metastases;

3. Cold sensitivity;

4. Cold agglutinin disease;

5. Cryoglobulinemia;

6. Cryofibrinogenemia;

7. Cold posttraumatic dystrophy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	12
Type:	Actual

Ethics review

Positive opinion

Date:	26-05-2010
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	NL2214

Register	ID
NTR-old	NTR2339
Other	METC Noord-Holland : M010-010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A