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

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The primary objective of this pilot study is 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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON35108

Source
ToetsingOnline

Brief title
FECtemp

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
alopecia, hair loss

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Eigen financiering

Intervention

Keyword: Alopecia, FEC chemotherapy, Scalp cooling, Temperature

Outcome measures

Primary outcome

Little is known about the influence of temperature on the outcome of scalp cooling. This pilot study will check the feasibility of the main study, after which specific parameters/outcome will be defined. Hair loss will be measured using the World Health Organisation (WHO) grading system for alopecia and asking the patient whether or not a wig or shawl is required.

Secondary outcome

n.v.t.

Study description

Background summary

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 the most impact. Several factors may contribute to the severety of hair loss, including dose, drug schedule, combinations with other cytotoxic agents as well as hair care practices. Research shows scalp cooling is often an effective method to prevent chemotherapy-induced hair loss. Data on parameters that can affect the effect of scalp cooling are scarce. Scalp skin temperature, scalp skin perfusion, liverfunction and scalp cooling time can possibly contribute and have to be taken into account in improving the protocol for scalp cooling during administration of chemotherapy.

Study objective

The primary objective of this pilot study is 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

This is a single-centre observational pilot study. The study will be conducted in the outpatient chemotherapy clinic of the department of Internal Medicine of the Medical Centre Alkmaar. Patients will be asked to participate in the study at the time of their first contact with the oncology nurse to schedule their first chemotherapy. After providing informed consent, they will be followed for six consecutive outpatient visits.

Study burden and risks

The burden for patients is attaching the thermocouple to the skin using theatre glue and completing questionnaires.

There are no additional risks for participating patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Intravenous administered FEC-regimen with an epirubicine dose of 90 mg/m2 or more at 3-weekly intervals, age 18 years or more, written informed consent

Exclusion criteria

Boldness before the start of the study, hematological malignancies with generalized haematogenic metastases and clinical signs of scalp metastases

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-07-2010
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	14-05-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

Approved WMO

Date:	08-07-2010
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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
CCMO	NL31325.094.10