Pilot study: Dystrophic pathways in human hair follicles after chemotherapy

Published: 15-11-2013
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The objective of this study is to explore molecular damage-response pathways such as p53 expression in hair follicles after chemotherapy.

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-OMON40394

Source
ToetsingOnline

Brief title
Path-study

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, chemotherapy, hair follicle, pathway

Outcome measures

Primary outcome

Expression of damage-response pathways

Secondary outcome

NA

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 de most impact. Several factors may contribute to the severity of hair loss including dose, drug schedule, combinations with other cytotoxic agents as well as hair care practices. Research shows scalp cooling is an effective method to prevent chemotherapy induced hair loss. The exact working mechanism is unclear. Therefore we do not know why scalp cooling is effective in one patient but not in another.

Study objective

The objective of this study is to explore molecular damage-response pathways such as p53 expression in hair follicles after chemotherapy.

Study design

This is a multi-center observational study. The study will be conducted in the outpatient chemotherapy clinic of the department of internal medicine of the Medical Center Alkmaar. Patients will be asked to participate at the time of their first contact with the oncology nurse to schedule their first chemotherapy. After providing informed consent, hairs will be collected during the first chemotherapy course.

Study burden and risks

The burden for patients consists of collecting hairs.

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

- Female patients with breast cancer
- Age 18 years or more
- Written informed consent
- Indication for at leaust one cycle of intravenous administered Docetaxel-Adriamycin-Cyclofosfamide (TAC), Fluorouracil-Epirubicin-Cyclophosphamide (FEC) or Adriamycin-Cyclophosphamide (AC).

Exclusion criteria

- Use of scalp cooling

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):	01-12-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	25-02-2014
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

ID: 22244
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45436.094.13
OMON	NL-OMON22244