Pilot study: Dystrophyc pathways in human hair follicles after chemotherapy with or without scalp cooling.

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We will explore the influence of chemotherapy on hair follicles. Scalp cooling works, but not in every patient. When we understand the working mechanism of chemotherapy induced alopecia, we can possibly explain why scalp cooling works in one patient...

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

Summary

ID

NL-OMON45664

Source
ToetsingOnline

Brief title
PATH-2

Condition

- Breast neoplasms benign (incl nipple)

Synonym
Alopecia, Hair loss

Research involving
Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: eigen financiering

Intervention

Keyword: chemotherapy, Dystrophic pathway, Hair follicle, Scalp Cooling

Outcome measures

Primary outcome

The expression of apoptotic markers in the dystrophic pathway involved in

chemotherapy induced alopecia.

Secondary outcome

Differences in the dystrophic pathway in patients with and without scalp

cooling.

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

We will explore the influence of chemotherapy on hair follicles. Scalp cooling works, but not in every patient. When we understand the working mechanism of chemotherapy induced alopecia, we can possibly explain why scalp cooling works in one patient, but not in the other.

Study design

This is a mono-center observational pilot 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

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients with cancer
- Indication for at least one cycle docetaxel or paclitaxel

- Age 18 years or more
- Written informed consent

Exclusion criteria

NA

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):	16-03-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL59406.094.16