# Pilot studie: Dystrofische signaalpaden in haarfollikels na chemotherapie

No registrations found.

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

# **Summary**

### ID

NL-OMON22244

**Source** Nationaal Trial Register

Brief title PATH study

#### Health condition

Signaalpad, kaalheid, chemotherapie, hoofdhuidkoeling Pathway, alopecia, chemotherapy, scalp cooling

### **Sponsors and support**

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

### Intervention

### **Outcome measures**

#### **Primary outcome**

Expression of damage-response pathways

#### Secondary outcome

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# **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.

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

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 objective**

Damage response pathways can possibly explain the working mechanism of scalp cooling

#### Study design

Hair samples will be collected at different time points.

Hair samples will be collected at:

- t=0 (before treatment with chemotherapy)
- t=2 (two days after chemotherapy)
- t=4 (four days after chemotherapy)
- t=8 (eight days after chemotheray)
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t=12 (twelve days after chemotherapy)

t=16 (sixteen days after chemotherapy)

The study will end when no fluctuation is seen between the different time-points.

#### Intervention

This pilot study will explore molecular damage-response pathways such as p53 expression in hair follicles after chemotherapy. It is known that all patients treated wit TAC, FEC and AC (any combination chemotherapy schedule including an anthracycline) lose their hair within two to three weeks. This pilot study explores various time-points to detect whether p53 fluctuates between these time-point. If there is no fluctuation between the different time-points in ten patients, it is unlikely to detect any fluctuation when more patients are included.

# Contacts

#### Public

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# **Eligibility criteria**

## **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-

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Cyclofosfamide (TAC), Fluorouracil-Epirubicin-Cyclophosphamide (FEC) or Adriamycin-Cyclophosphamide (AC).

### **Exclusion criteria**

- Use of scalp cooling

# Study design

### Design

Control: N/A , unknown	
Allocation:	Non controlled trial
Intervention model:	Parallel
Study type:	Observational non invasive

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2013
Enrollment:	10
Туре:	Actual

# **Ethics review**

Positive opinion	
Date:	06-01-2014
Application type:	First submission

# **Study registrations**

# Followed up by the following (possibly more current) registration

ID: 40394

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Bron: ToetsingOnline Titel:

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

No registrations found.

# In other registers

Register	ID
NTR-new	NL4192
NTR-old	NTR4343
ССМО	NL45436.094.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40394

# **Study results**

Summary results

N/A