ISRCTN00283877 https://doi.org/10.1186/ISRCTN00283877

A multicentre study to determine the efficacy and patient acceptability of scalp cooling in the prevention of docetaxel-induced hair loss

Submission date 12/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2005	**Overall study status** Completed	
Last Edited 19/09/2008	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.geefhaareenkans.info

Contact information

Type(s)
Scientific

Contact name
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Contact details
Zernikestraat 29
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5612 HZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR90

Study information

Scientific Title

Acronym
SCALP

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hair loss due to chemotherapy

Interventions
Scalp cooling with various cooling times or cooling temperatures.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Efficacy and patient acceptability of scalp cooling.

Secondary outcome measures
Relation of the efficacy of scalp cooling and:
1. Prior treatment with cytostatic agents
2. Prior or parallel hormonal treatment
3. Prior radiotherapy of the scalp
4. Liver metastases and/or liver or kidney function disorder
5. Type of hair (determined by race)

Overall study start date
25/07/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Intravenous administered docetaxel regimes
2. Age 18 years or more
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
260

Key exclusion criteria
1. Boldness before the start of the study
2. Haematological malignancies with generalised haematogenic metastases (e.g. lymphoma, leukaemia and multiple myeloma) and if in those conditions chemotherapy is given with a curative intent
3. Clinical signs of scalp metastases
4. Cold sensitivity
5. Cold agglutinin disease
6. Cryoglobulinaemia
7. Cryofibrinogenaemia

Date of first enrolment
25/07/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Zernikestraat 29
Eindhoven
Netherlands
5612 HZ

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
University/education

Website
http://www.lumc.nl/english/start_english.html

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Charity

Funder Name
Sanofi Aventis (The Netherlands)

Funder Name
Comprehensive Cancer Centre, South Region (Integraal Kankercentrum Zuid) (The Netherlands)

Funder Name
Interzol (The Netherlands)

Funder Name
Foundation for the Support of the Care of Cancer, South Region (Stichting Ondersteuning Regionale Kankerzorg Zuid) (The Netherlands)

Funder Name
Mitialto Foundation (Stichting Mitialto) (The Netherlands)

Funder Name
VGZ Eindhoven (The Netherlands)

Funder Name
Catharinaziekenhuis Eindhoven Scientific Funds (Wetenschappelijk Fonds Catharinaziekenhuis Eindhoven) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration