

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
Registration date 12/09/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 19/09/2008	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Corina van den Hurk

Contact details
Zernikestraat 29
Eindhoven
Netherlands
5612 HZ

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Treatment

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(s)

Efficacy and patient acceptability of scalp cooling.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes