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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
12/09/2005		Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/09/2005 Last Edited	Completed Condition category	Results		
		Individual participant data		
19/09/2008	Cancer	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

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

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