

A study to determine the effect of post-infusion cooling time in the high dose 5-fluorouracil, 4-epidoxorubicin and cyclophosphamide (FEC)-regime

Submission date 21/07/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/07/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/11/2008	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Integraal Kankercentrum Zuid
Sector Onderzoek
Zernikestraat 29
Eindhoven
Netherlands
5612 HZ

Additional identifiers

Protocol serial number

NTR680

Study information

Scientific Title

Acronym

POSTFEC

Study objectives

20 to 30% improvement of scalp cooling results due to longer post-infusion cooling times.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer, hair loss

Interventions

Randomly assigned post-infusion cooling time of 90 or 150 minutes

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

5-fluorouracil, 4-epidoxorubicin, cyclophosphamide, epirubicin

Primary outcome(s)

Amount of hair loss

Key secondary outcome(s))

1. Acceptability of scalp cooling
2. Relation of the efficacy of scalp cooling with prior chemotherapy, radiotherapy or hormonal treatment, liver or kidney function disorder and type of hair
3. Quality of life during chemotherapy

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Intravenously administered FEC-regimen with an epirubicin dose of 90 mg/m² or more at three-weekly intervals
2. Aged 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

Female

Key exclusion criteria

1. Baldness before the start of the study
2. Hematological malignancies with generalized haematogenic metastases and if in those conditions chemotherapy is given with a curative intent
3. Clinical signs of scalp metastases

Date of first enrolment

01/06/2006

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Integraal Kankercentrum Zuid

Eindhoven

Netherlands

5612 HZ

Sponsor information

Organisation

Medical Centre Alkmaar (Medisch Centrum Alkmaar) (The Netherlands)

ROR

<https://ror.org/04vccmr34>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Comprehensive Cancer Centre, South Region (Integraal Kankercentrum Zuid)

Funder Name

Interzol

Funder Name

Mitialto Foundation (Stichting Mitialto)

Funder Name

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

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

