ISRCTN97879847 https://doi.org/10.1186/ISRCTN97879847

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

Registration date
21/07/2006

Last Edited
04/11/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
Amount of hair loss

Secondary outcome measures
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

Overall study start date
01/06/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Intravenously administered FEC-regimen with an epirubicin dose of 90 mg/m^2 or more at three-weekly intervals
2. Aged 18 years or more
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
130

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)

Sponsor details
P.O. Box 501
Alkmaar
Netherlands
1800 AM

Sponsor type
Hospital/treatment centre

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

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