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Scalp cooling: a randomised trial to assess the efficacy and comfort of two forms of scalp cooling in breast cancer patients who are receiving FEC chemotherapy

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/12/2015	**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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0254119954

Study information

Scientific Title
Scalp cooling: a randomised trial to assess the efficacy and comfort of two forms of scalp cooling in breast cancer patients who are receiving FEC chemotherapy

Study objectives
To assess the efficacy and comfort of the Paxman scalp cooler versus the Penguin cold cap system. To evaluate patients' views and response to scalp cooling and to provide health care professionals with informed research of the benefits of scalp cooling and the appropriate device.

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)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cancer: Breast

Interventions
Randomised controlled trial to compare Paxman scalp cooler versus the Penguin cold cap system

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/01/2003

Completion date
01/11/2005

Eligibility

Key inclusion criteria
Sufficient hair to assess hair loss, willing to have either systems and aware of the time taken to use the scalp cooling, receiving FEC chemotherapy for breast cancer.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
02/01/2003

Date of final enrolment
01/11/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

The Ipswich Hospital NHS Trust
Ipswich, Suffolk
United Kingdom
IP4 5PD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Ipswich Hospital NHS Trust

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