

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
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 07/12/2015	Condition category Cancer	☐ Statistical analysis plan
		☐ Results
		☐ 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

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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**

United Kingdom

England

Study participating centre

The Ipswich Hospital NHS Trust

Ipswich, Suffolk

United Kingdom

IP4 5PD

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

Ipswich Hospital NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration