A study to look at the effects of a hydrolat spray to palliate hot flushes in women being treated for breast cancer

Submission date Recruitment status Prospectively registered 28/09/2007 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 28/09/2007 Completed [X] Results [] Individual participant data Last Edited Condition category Signs and Symptoms 18/10/2011

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number N0258184657

Study information

Scientific Title

Study objectives

Hot flushes are a common side effect of treatment for breast cancer. Research has shown that having more problematic hot flushes and night sweats was associated with more anxiety and sleep problems, poorer emotional and social functioning and worse body image. Current advice suggests cool sprays and moist wipes to lower skin temperature. Although anecdotal evidence for the beneficial effects of hydrolats is quoted in text books and aromatherapy teaching programmes, no research into specific effects for hot flushes has been found. The principle research question is to establish whether a peppermint and neroli hydrolat spray is preferred by woman over a distilled water spray to help palliate the unpleasant effects of hot flushes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomized single blinded crossover study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Signs and Symptoms: Hot flushes

Interventions

Randomized single blinded crossover study of two sprays

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The number of women choosing a hydrolat spray in preference to a water spray to palliate hot flushes.

Key secondary outcome(s))

Not provided at time of registration

Completion date

15/01/2007

Eligibility

Key inclusion criteria

Any woman suffering from hot flushes as a result of treatment for breast cancer.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

16/08/2006

Date of final enrolment

15/01/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Nutrition and Dietetic Department London

London United Kingdom SW3 6JJ

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

The Royal Marsden NHS Foundation Trust (UK)

Funder Name

NHS R&D Support Funding

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?
Results article	results	01/11/2008		Yes	No