

A randomised trial of the use of hypnosis to affect menopausal vasomotor symptoms in women with early stage breast cancer, using a waiting list control

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/02/2020	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0013145883

Study information

Scientific Title

A randomised trial of the use of hypnosis to affect menopausal vasomotor symptoms in women with early stage breast cancer, using a waiting list control

Study objectives

Is hypnosis an effective treatment for vasomotor symptoms of the menopause in women with early stage breast cancer?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 23/03/10: approved by St Thomas Hospital LREC.

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

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 trial with waiting list control: patients complaining of vasomotor symptoms of hot flushes/ night sweats have 3 sessions of hypnosis over 3 weeks. Control arm: similar treatment but delayed for 3 weeks. Both groups to keep diaries of vasomotor events and complete QOL questionnaires at strategic points through a 16-week period. On-going follow-up where possible.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Reduction in frequency or intensity of flushing compared with waiting list control. Treatment effects and improvements will be maintained for over 3 months for the combined group.

Secondary outcome measures

Sustained effect passed 4 months as a secondary end-point.

Overall study start date

01/09/2002

Completion date

01/09/2003

Eligibility

Key inclusion criteria

Women who suffer from vasomotor symptoms of menopause who fit the criteria for the national HRT & Breast Cancer Trial and who are randomised to non-hormonal intervention; or women who fit the criteria who are not in the HRT Trial at all.

Inclusion criteria:

1. Have had proven stage I/II breast cancer with no clinical evidence of recurrence (ER status where available will be documented but not used as an inclusion or exclusion criteria).
2. Have either: been amenorrhoeic for 36 months (including women who have had radiation or chemical induced ovarian suppression) irrespective of menopausal status at time of diagnosis or have had a surgical bilateral oophorectomy and are therefore eligible at any time after surgery.
3. Are experiencing vasomotor symptoms (i.e. hot flushes or night sweats) with or without vaginal dryness.
4. Have signed the informed consent form, including willingness to co-operate in assigned treatment and follow up.

All women who do not fall into the categories detailed in the ineligibility section below, will be eligible irrespective of current/previous treatment for breast cancer.

Participant type(s)

Patient

Age group

Not Specified

Sex

Female

Target number of participants

50 subjects

Key exclusion criteria

1. Are currently taking HRT, or have received oral or transdermal HRT within the last three months, or have received an HRT implant within the last 5 years
2. Are currently receiving chemotherapy, due to a theoretical increase in risk of venous thromboembolic disease (Pritchard et al 1996)
3. Are receiving GnRHa eg Zoladex, with less than 2 years treatment remaining. The amenorrhoeic state induced by Zoladex is completely reversible. Therefore, patients with less than 2 years treatment remaining would not be eligible for the full 2 year term of the intended HRT treatment
4. Are pregnant

or have:

5. DCIS or LCIS alone
6. Recurrent breast cancer
7. Concomitant or previous other malignancy except non-melanoma skin cancer or in situ cancer of the cervix.
8. Undiagnosed post-menopausal bleeding
9. Severe, active liver disease with abnormal liver function tests
10. A history of alcohol, drug or chemical abuse
11. A history of DVT/PE or retinal vein thrombosis - patients with abnormal fibrinolysis or coagulation must be excluded. Patients with either thrombophlebitis or superficial phlebitis alone can be included
12. Acute, intermittent porphyria

Date of first enrolment

01/09/2002

Date of final enrolment

01/09/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Clinical Oncology

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
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Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)**Funder type**

Government

Funder Name

Guy's and St. Thomas' NHS Foundation Trust (UK) Own Account

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