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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	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/02/2020	**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
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 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
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SE1 7EH

Sponsor information

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

Sponsor details
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Sponsor type
Government

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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