

Venlafaxine and gabapentin for the management of hot flashes in breast cancer survivors: a randomized crossover trial

Submission date 10/05/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/06/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/01/2011	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

N/A

Study information

Scientific Title

Acronym

Vibrant Study

Study objectives

We hypothesize that breast cancer survivors will prefer gabapentin over venlafaxine based on perceived lower side effects and equivalent efficacy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Mount Sinai Hospital Research Ethics Board initial approval on 6th July 2006 (last continued approval is 8th July 2008) (ref: MSH REB # 06-0145-A)

Study design

Randomized crossover open-label trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Venlafaxine versus gabapentin

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gabapentin, venlafaxine

Primary outcome measure

To compare patient preference for venlafaxine versus gabapentin in a randomized crossover single blind trial

Secondary outcome measures

1. To compare hot flash frequency, severity, and composite scores
2. To compare quality of life measured using the medical outcomes study-short form 36 (MOS-SF36) and mood measured using the profile of mood states (POMS)
3. To compare toxicities
4. To correlate patient preferences with standard outcome measurements

Overall study start date

01/07/2006

Completion date

01/07/2009

Eligibility**Key inclusion criteria**

1. Women with a history of breast cancer, ductal carcinoma in situ (DCIS), or lobular carcinoma in situ (LCIS) (currently without evidence of malignant disease and who have completed chemotherapy or radiation therapy for 8 weeks)
2. Age 18 or above
3. Bothersome hot flashes (at least 14 hot flashes per week and of sufficient severity for the patients to desire pharmacologic intervention)
4. Presence of hot flashes for at least one month prior to study entry
5. Life expectancy of at least six months
6. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1
7. Normal creatinine clearance

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

120

Key exclusion criteria

1. Previous use of venlafaxine or the use of any other antidepressants (including St. John's Wort) within a year prior to study entry
2. Current (less than or equal to 2 weeks) or planned use of other agents for the treatment of

hot flashes

3. Calcium channel antagonist or gabapentin within two weeks of study entry

4. Tamoxifen, aromatase inhibitors and gonadotropin-releasing hormone (GnRH) analogues are allowed unless started less than or equal to 4 weeks and or if the plan is to stop these agents during the study period (i.e. 12 weeks)

Date of first enrolment

01/07/2006

Date of final enrolment

01/07/2009

Locations

Countries of recruitment

Canada

Study participating centre

600 University Avenue

Toronto

Canada

M5G 1X5

Sponsor information

Organisation

Canadian Breast Cancer Foundation

Sponsor details

600 University Avenue

Room 1286

Toronto

Canada

M5C 2N8

Sponsor type

Charity

Website

<http://www.cbcf.org/ontario>

Funder(s)

Funder type

Charity

Funder Name

Canadian Breast Cancer Foundation (Canada)

Alternative Name(s)

Société canadienne du cancer, cancersociety, Canadian Cancer Society (Canada), CCS, SCC

Funding Body Type

Government organisation

Funding Body Subtype

Associations and societies (private and public)

Location

Canada

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/12/2010		Yes	No