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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/06/2006	**Overall study status** Completed	
Last Edited 27/01/2011	**Condition category** Cancer	

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
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 intial 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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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

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

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