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Stellate ganglion block reduces hot flushes and night awakenings in breast cancer survivors: a pilot study

Submission date	Recruitment status	[_] Prospectively registered
19/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/06/2008	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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60195

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
The hypothesis is that stellate ganglion block decreases hot flushes and night awakenings in breast cancer survivors. The current project is to prove that hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Alexian Brothers Hospital Network Institutional Review Board on the 5th October 2006.

Study design
Interventional, single-centre, single arm, non-placebo controlled trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hot flushes, night awakenings

Interventions
The intervention used was a stellate ganglion block at C6. Each patient had 1 - 2 blocks depending on the patient. Follow up was from before treatment to 12 weeks post-initial treatment. Observed occurrences were documented before and after intervention.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Hot flush qualitative scores - mild to very severe
2. Quantitative hot flush occurrences per day
3. Night awakening per night

Data was collected before the intervention and daily after the intervention for 12 weeks.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2007

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. 30 - 70 year old female breast cancer survivors
2. American Society of Anaesthesiologists (ASA) scores 3 or below

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
13

Key exclusion criteria
Does not comply with the above inclusion criteria.

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
United States of America

Study participating centre

2260 W. Higgins Rd.
Hoffman Estates
United States of America
60195

Sponsor information

Organisation
Advanced Pain Centers (USA)

Sponsor details
2260 W. Higgins Rd.
Ste 101
Hoffman Estates
United States of America
60195

Sponsor type
Hospital/treatment centre

Website
http://www.painmngt.com/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (USA)

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	01/06/2008		Yes	No