

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

Submission date
19/04/2008

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
08/05/2008

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
03/06/2008

Condition category
Urological and Genital Diseases

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Eugene Lipov

Contact details

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Additional identifiers

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (USA)

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	01/06/2008		Yes	No