Short-term Efficacy of Stellate Ganglion Block in Men to reduce Hot Flushes related to Androgen Deprivation Therapy

Published: 21-02-2014
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To assess the short-term efficacy of stellate ganglion block on hot flush reduction versus sham procedure

Ethical review	Approved WMO
Status	Will not start
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON38339

Source
ToetsingOnline

Brief title
SBG for hot flushes in men treated with ADT

Condition

- Hypothalamus and pituitary gland disorders

Synonym
hot flushes

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: door onderzoeksafdelingen (interne geneeskunde/anesthesie gefinancieerd

Intervention

Keyword: androgen deprivation therapy, hot flushes, prostate cancer, stellate ganglion block

Outcome measures

Primary outcome

Hot flush score: percentage reduction in hot flush score and the number of

subjects reaching a flush score reduction >50%.

Hot Flush score = mean daily flush frequency x flush severity

(flush severity = mean severity score of every flush on a 1-4 scale)

Secondary outcome

Quality of life, measured with 3 questionnaires:

a. Hot Flash-Related Daily Interference Scale (HFRDIS)

b. Epworth Sleepiness Scale (ESS)

c. PSQI (Pittsburgh Sleep Quality Index)

Study description

Background summary

Androgen deprivation therapy (ADT) is widely used as standard therapy in the treatment of locally advanced and metastatic prostate cancer. Hot flushes and night sweats are one of the main side-effects of ADT. There are no succesfull and well-tolerable treatment options available. A possible treatment for hot flushes is stellate-ganglion block (SGB), used as a means of interrupting parts of the sympathetic nervous system involved in temperature regulation. Stellate-ganglion blocks have been done safely for more than 60 years in patients for various pain conditions. Several studies have demonstated promising results in women with severe flushes. It has not been studied in men, but in theory it should be just as effective.

Study objective

To assess the short-term efficacy of stellate ganglion block on hot flush

reduction versus sham procedure

Study design

-Single center: Rijnstate Hospital, Arnhem, The Netherlands
-Setting: outpatient setting
-Study period: 1-1-2014 to 1-11-2014
-Screening: Recording of flushes by diary for a period of 7 days. Minimum of 10 flushes per day or a hot flush score of 15 or more is required
-After inclusion:
-Week 0:
Start recording of flushes by diary 24 hrs/day
Questionnaires: HFRDIS, PSQI, ESS
Venous blood samples of LH, FSH, estradiol, SHBG, albumin and testosterone
-Week 1:
Day 1: Randomization and SGB/sham procedure will be performed by Dr Kallewaard, anesthesiologist
-Week 1-4:
Continue recording of flushes by diary
-Week 4;
Questionnaires: HFRDIS, PSQI, ESS
Venous blood samples of LH, FSH, estradiol, SHBG, albumin and testosterone

Intervention

stellate ganglion block versus sham-procedure

Study burden and risks

Burden mainly consists of reporting in the diary. The risks are very small and the procedure minimally invasive.

Contacts

Public
Rijnstate Ziekenhuis

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Scientific
Rijnstate Ziekenhuis

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- General criteria;;Male;Age: >18 years;Mean daily flush frequency of 10 or more, and a mean hot flush score of 15 or higher;Treatment with ADT because of prostate cancer;Absence of any other cause of flushing

Exclusion criteria

- Use of medication that affects flushing:;o estrogens, progestogens, clonidine, naloxone, paroxetine, fluoxetine, venlaflaxine, gabapentin, LHRH receptor antagonist;- Still receiving chemotherapy of radiotherapy;- Psychiatric disease;- Any unstable concurrent disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	bupivacaine
Generic name:	bupivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-02-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-06-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-005325-23-NL
CCMO	NL46979.091.13