Short-term Efficacy of Stellate Ganglion Block to reduce Hot Flushes in women

Published: 19-10-2016
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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	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON44088

Source
ToetsingOnline

Brief title
SGB for hot flushes in women

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: onderzoeksafdelingen interne geneeskunde en anesthesiologie

Intervention

Keyword: hot flushes, menopause, 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 5 questionnaires:

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

b. Epworth Sleepiness Scale (ESS)

c. PSQI (Pittsburgh Sleep Quality Index)

d. MENQOL (Menopause-Specific Quality of Life)

e. CES-D (Center for Epidemiologic Studies Depression Scale)

Study description

Background summary

Hot flushes are the most common symptom of menopause for which postmenopausal (PMP) women seek medical help. In 20% of PMP women hot flushes can persist for up to 15 years. Some women will have hot flushes several times a week, whereas others experience symptoms every hour or more. Flushing, in addition to discomforting effects in daytime, may also disrupt sleep and thereby cause chronic fatigue, irritability and depression. About 20% of PMP women find the symptoms intolerable.

A possible treatment for hot flushes is stellate-ganglion block (SGB), used as a means to interrupt parts of the sympathetic nervous system involved in

temperature regulation. Stellate-ganglion blocks have been performed safely for more than 60 years in patients for various pain conditions. Several studies have demonstated promising results in women with severe flushes.

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
-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, MENQOL, CES-D
-Week 1:
Day 1: Randomization. SGB/sham procedure will be performed by Dr Kallewaard, anesthesiologist
- Week2; week 4: week 8; week 12; week 26 = beginning of the week questionnaires: HFRDIS, PSQI, ESS, MENQOL, CES-D
- Week2; week 4: week 8; week 12; week 26 = all week recording of hot flushes frequency and severity
- week 4: taking bloodsample to check hormones related to hot flushes and menopause

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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

female
age 30-70
mean daily flush frequency >9
hot flush score >14
absence of reasons for flushing other than post-menopausal (spontaneous or medical induced)
postmenopausal > 1 year in healthy women (e.g. spontaneous)

Exclusion criteria

- Use of medication that affects flushing:
estrogens, progestogens, clonidine, naloxone, paroxetine, fluoxetine, venlaflaxine, gabapentin, LHRH receptor antagonist
- Still receiving chemotherapy of radiotherapy
- allergy for contrast dye or local anesthetics of amide type
- active concurrent somatic disease
- active concurrent psychiatric disease

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2017
Enrollment:	76
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	anhydrous bupivacaine hydrochloride 0.5%
Generic name:	Bupivacaine 0.5%
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-10-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-12-2016
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-11-2017
Application type:	Amendment
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	EUCTR2016-001180-36-NL
ClinicalTrials.gov	NCT02295163
CCMO	NL54465.091.16