The effects of Highly Selective Dorsal Sympathectomy on blushing and fear of blushing

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON39243

Source
ToetsingOnline

Brief title
Effects of HSDS

Condition

- Anxiety disorders and symptoms
- Nervous system, skull and spine therapeutic procedures

Synonym
erythrophobia, fear of blushing

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fear of blushing, incapacitating blushing, social anxiety, sympathectomy

Outcome measures

Primary outcome

Fear of blushing subscale of the Blushing, Trembling and Sweating Questionnaire (BTSQ; Bögels & Reith, 1999). This questionnaire assesses fear of showing somatic symptoms.

Secondary outcome

Daily blushing will be measured with the use of visual analogue scales.

For a comprehensive description of the sample, the subjects will complete the Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977); the Social Interaction Anxiety Scale (SIAS; Mattick & Clarke, 1998); the brief Fear of Negative Evaluation Scale (BFNE; Leary, 1983); the social phobia subscale of the Fear Questionnaire (FQ; Marks and Mathews, 1979); and the nineteen-item version of the Blushing Propensity Scale (BPS; Bögels, Alberts & de Jong, 1996)

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Implicit blush associations will be assessed using a Implicit Association Test (Glashouwer, de Jong, Dijk & Buwalda, 2010); interpretations using the Blush Cognitions Questionnaire (Dijk, et al., 2009) and a recognition task (Dulken, 2010) . The SCID-I-I/P (Spitzer et al., 1992) will be used as a diagnostic interview to examine psychopathology.

Study description

Background summary

Fear of blushing is a disabling disorder. People who fear their blushes do so in many social situations and consequently avoid those situations or endure them with intense fears. Although several psychological interventions are available and effective, the clinical impression is that people with fear of blushing do not seek professional help easily and when they do, their fear is often not well recognised. Furthermore, people with fear of blushing often see their complaint as mainly physiological instead of psychological, which may explain the popularity of an operation to remove the ability to blush altogether by means of the surgical cutting through of the sympathetic nerve. Despite its popularity, the effectiveness of this surgical intervention has never been tested in a randomized controlled trial and the methodological design of most studies that tested the effectiveness of the intervention is poor. Furthermore, only few studies actually measure if the operation reduced anxiety complaints but none of them actually measured fear of blushing. The current study is set up to fill this gap in the literature.

Study objective

The first aim is to test the effect of the surgical intervention for fear of blushing in a randomized controlled trail consisting of a robot-assisted highly selective dorsal sympathectomy and a waiting list control group.

There are several outcome measures to test the effectiveness of the intervention. Fear of blushing and social fears will be measured using standard scales. Blush intensity will be measured subjectively using visual analogue scales.

Also, the effect the intervention on several information processing and cognitive biases will be tested, since these are known to play a key role in maintaining fears. That is, beliefs about blushing, implicit associations and interpretation biases will be measured.

Furthermore, all subjects will receive a diagnostic interview to asses their psychopathology both before and after treatment.

Study design

The design is quasi experimental: only people who already applied for the operation will be included in the study. Within this group of people, the study is a randomized controlled trail consisting of two arms: sympathectomy (HSDS) and a waiting list (WL). The duration of the study is 20 weeks and the study is

being conducted at the VU medical centre (HSDS) and the Psypoli of the UvA (diagnostics). There are three moments of measurement: before the intervention/waiting time (t1), right after the intervention/waiting time (t2) and a 3 month follow up (t3).

Intervention

Operative technique
Bilateral HSDS is performed in a single operative setting. All procedures are performed by the same surgical team and a standard surgical protocol was followed throughout the study period. General anaesthesia using single-lumen tube endotracheal intubation and low volume-high frequency ventilation is applied in all patients. Patients are placed in a lateral decubitus position. Three thoracoscopic ports, one of 13-mm diameter situated in the 6th intercostal space at the mid axillary line and two 8-mm ports in the 4th intercostal space, 5 cm anterior, and 5 cm more posterior to the mid axillary line, respectively. The Da Vinci robot (Intuitive Surgical, Inc. Sunnyvale, CA, USA) is positioned near the head of the patient. All patients undergo HSDS by division of their rami communicantes efferentes grisei from the T2 ganglion to the T4 ganglion using robotic manipulation, a 30° 3-D thoracoscope and bipolar electrocautery. The mediastinal pleura is opened and the anatomy of the whole upper part of the sympathetic chain and its rami communicantes are identified. The main trunk is mobilised and preserved and the efferent rami communicantes from T2 to T4 are interrupted and removed 2 cm laterally in all patients. If present, accessory fibres and Kuntz*s nerve are coagulated. A chest tube of 16 French is inserted to be removed the next day. The robot is retracted at closure and the patient is turned on the contra lateral side for an identical procedure. The total operating time is 60 minutes, hospital stay 2 days.

Study burden and risks

The measurements are time consuming but there are no risks involved. All subjects are on the waiting list for HSDS, so the operation itself cannot be considered a risk of the study (since subjects will also undergo this treatment without participating in the study). Nevertheless, the benefits of the Highly Selective Dorsal sympathectomy (HSDS) include the immediate disappearance of blushing and, possibly, blushing anxiety. The risks include the introduction of compensatory sweating (35% of the cases), Horner Syndrome (2.5% of the cases), postoperative pain (5 % of the cases) and pneumothorax (5% of the cases).

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

Incapacitating facial blushing.

Exclusion criteria

Being under 18. Furthermore, people are not allowed to undergo sympathetic surgery when they have: 1) A history of reconstructive chest wall surgery; 2) Pulmonary or (unsuccessful) sympathetic surgery including iatrogenic Harlequin syndrome; 3) Acceptable results with drug treatment; 4) ASA classification greater than 1.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-09-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	21-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25945
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL31227.029.11