Effectiviteit van een operatie voor het behandelen van blozen en bloosangst.

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HDSD reduces blushing and fear of blushing. HDSD recudes social anxiety to a lesser extend. HDSD does not effect implicit measures.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25945

Bron
NTR

Verkorte titel
Effects of HSDS

Aandoening

Pathological blushing and fear of blushing

Ondersteuning

Primaire sponsor: University of Amsterdam, VU Medical Center
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Fear of blushing subscale of the Blushing, Trembling and Sweating Questionaire (BTSQ; Bögels & Reith, 1999). This questionnaire assesses fear of showing somatic symptoms;
2. Cheek coloration will be used to index blushing and will be recorded from a

plethysmograph transducer fastened to the skin with tape for sensitive skin on the zygomatic bone near the inner canthus. As a second measure, cheek temperature will be monitored unilaterally with a semi-conductive thermistor fastened to the skin, just below the plethysmograph transducer. Blushing will be measured during a baseline rest period and during a social task;
3. Social anxiety will be measured with 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).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Examine the effectiveness of robot-assisted highly selective dorsal sympathectomy (HSDS) on the physiological blush response and social anxiety due to blushing. Despite its popularity, the effectiveness of this surgical intervention has never been tested in a randomized controlled trial and the methodological set up of most studies that tested the effectiveness of the intervention is poor.

Objective:

The main aim of the study is to compare the effects of the intervention with a waiting list (WL) and examine the reduction in social anxiety, fear of blushing and the physiological blush response. A second aim is to test the effects of the treatment on depression and cognitive biases.

Study design:

The study is a randomized clinical trial with two conditions (HSDS and WL) and three measurements (before treatment/WL period, after treatment/WL period and at a 3 months follow-up).

Study population:

The study population consists of people who applied for HSDS at the VU medical centre (age>18).

Intervention:

The HSDS is a minimal invasive endoscopical procedure in which bilaterally the efferent rami communicantes of the thoracic sympathetic ganglion T2 to T4 are divided.

Main study parameters/endpoints:

The main study parameters are the reduction of social anxiety, fear of blushing and the actual physiological blush response.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

All subjects are on the waiting list for HSDS, so the operation itself cannot be considered a risk of the study (the subjects will also undergo this treatment without participating in the study). Benefits are a possible shortening of the waiting period for HSDS
and the assessments may help subjects gain a better understanding of their complaints.

Doel van het onderzoek

HDSD reduces blushing and fear of blushing. HDSD recudes social anxiety to a lesser extend. HDSD does not effect implicit measures.

Onderzoeksopzet

Both groups will be measured three times:

1. Before the opertation/waiting list period (SCID, Blushing, BTSQ, BPS, SIAS, BFNE, FQ, CED-D, IAT, Blush congnitions, Interpretation Bias);

2. After the operation/waiting list (same measurments as t1 but without SCID);

3. At a three months follow us (same measurents as t1 but without Blushing).

Onderzoeksproduct en/of interventie

Bilateral HSDS is performed in a single operative setting. All procedures are performed by the same surgical team and a standard surgical protocol will be 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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Incapacitating facial blushing.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Being under 18;

Furthermore, people are not allowed to undergo sympathetic surgery when they have:

2. A history of reconstructive chest wall surgery;

3. Pulmonary or (unsuccessful) sympathetic surgery including iatrogenic Harlequin syndrome;

4. Acceptable results with drug treatment;

5. ASA classification greater than 1.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	44
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-03-2013

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39243
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3726
NTR-old	NTR3889
CCMO	NL31227.029.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39243

Resultaten

Samenvatting resultaten
N/A