

Low versus high dose Botulinum Toxin A in Axillary Hyperhidrosis

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/05/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0065149382

Study information

Scientific Title

Low versus high dose Botulinum Toxin A in Axillary Hyperhidrosis

Study objectives

To compare the efficacy of fewer injections of a higher dose (5U) to the conventional practice of numerous smaller dose (2U) injections. We aim to compare the total amount and area of sweating of these two regimes and their comfort for the patient.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled intra-individual single-blinded study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Signs and Symptoms: Axillary hyperhidrosis

Interventions

Higher dose (5U) vs conventional practice of numerous smaller dose (2U) injections

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Botulinum Toxin A

Primary outcome measure

Patient comparison of the total amount and area of sweating by gravimetric (weighing total amount of sweat) and starch-iodine (demarcating area of sweat) testing respectively between the axillae treated with 2U BTX-A per injection to that treated with 5U BTX-A

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2004

Completion date

01/03/2006

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Approximately 28 patients will be recruited

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2004

Date of final enrolment

01/03/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Sunderland Royal Hospital

Sunderland

United Kingdom

SR4 7TP

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

City Hospitals Sunderland NHS Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration