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Low versus high dose Botulinum Toxin A in Axillary Hyperhidrosis

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

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
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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