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Low versus high dose Botulinum Toxin A in Axillary Hyperhidrosis

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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled intra-individual single-blinded study

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/03/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Sunderland Royal Hospital
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
City Hospitals Sunderland NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration