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Botulinum toxin-A in sensory urgency

Submission date	Recruitment status	[X] Prospectively registered
05/07/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/01/2012	Urological and Genital Diseases	

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
BTXSENS

Study information

Scientific Title

Study objectives
Botulinum toxin-A will improve symptoms related to sensory urgency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No Ethics Approval as of 05/07/2006 - Guy's and St Thomas research ethics committee will review the protocol

Study design
Randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sensory urgency, overactive bladder

Interventions
Intervention group: Botulinum toxin-A will be administered at 100-150 units.
Control group: Placebo (normal saline solution) will be administered in the same way as the intervention group.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Botulinum toxin-A

Primary outcome measure
Urodynamics: Maximum cystometric capacity

Secondary outcome measures

1. Three day bladder voiding diaries to assess urinary frequency, urgency and incontinence episodes
2. Validated quality of life questionnaires:
a. Kings Health Questionnaire (KHQ)
b. Incontinence Impact Questionnaire short form (IIQ-7)
c. Urogenital Distress Inventory short form (UDI-6)

Overall study start date
01/10/2006

Completion date
01/10/2009

Eligibility

Key inclusion criteria
1. Informed consent to participate
2. Male and females 18 to 80 years of age
3. Symptoms of overactive bladder
4. Refractory to anticholinergics
5. No evidence of detrusor overactivity on urodynamic studies

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
64 patients

Key exclusion criteria
1. Pregnancy or planned pregnancy in the next year
2. Breast feeding
3. Painful bladder syndrome or interstitial cystitis
4. Evidence of significant outflow obstruction
5. Indwelling catheter
6. Previous bladder surgery e.g. augmentation cystoplasty
7. Previous urological use of botulinum toxin

8. Other bladder pathology e.g. tumours, active infection
9. Proven detrusor overactivity
10. Current anticoagulation treatment e.g. heparin, warfarin

Date of first enrolment
01/10/2006

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Urology
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's and St Thomas' NHS Trust (UK)

Sponsor details
Research & Development Department
Counting House
Guys Hospital
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Unrestricted educational grant from Allergan, Ltd

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2011		Yes	No