ISRCTN57577615 https://doi.org/10.1186/ISRCTN57577615

# 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**
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 hypothesis
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

## Condition
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

### Overall study end date
01/10/2009

## Eligibility

### Participant 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

### Participant 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

### Recruitment start date
01/10/2006

### Recruitment end date
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 |