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 of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Mr Mohammad Khan

**Contact details**
Department of Urology
1st floor Thomas Guy House
Guys Hospital
London
United Kingdom
SE1 9RT

## Additional identifiers

**Protocol serial number**
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

### Study type(s)
Treatment

### 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(s)
Urodynamics: Maximum cystometric capacity

### Key secondary outcome(s))
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)

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
80 years

### Sex
All

### 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
United Kingdom

England

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

# Sponsor information

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

**ROR**
https://ror.org/00j161312

# Funder(s)

**Funder type**
Industry

**Funder Name**
Unrestricted educational grant from Allergan, Ltd

# Results and Publications

## 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 |