

Botulinum toxin-A in sensory urgency

Submission date 05/07/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 21/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/01/2012	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
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

Primary study design

Interventional

Study design

Randomised double blind placebo controlled trial

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