ISRCTN16995641 https://doi.org/10.1186/ISRCTN16995641

The effects of botulinum toxin A on patients with idiopathic detrusor overactivity. A double-blind, randomised, placebo-controlled trial.

Submission date	Recruitment status
16/09/2005	No longer recruiting
Registration date	**Overall study status**
19/10/2005	Completed
Last Edited	**Condition category**
13/10/2009	Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BOTOX Study Protocol

Study information

Scientific Title

Study objectives
Botulinum toxin A at 200 units will improve urinary frequency, urgency and incontinence episodes, urodynamic variables and quality of life compared with placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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
Overactive bladder symptoms and idiopathic detrusor overactivity.

Interventions
Baseline: voiding diary, urodynamics, quality of life (QoL) questionnaires.
Flexible cystoscopy and 3 bladder biopsies followed by injection of either 200 u of botulinum toxin A (20 injections at 10 u/ml/site) versus placebo (normal saline 20 injections at 1 ml/site.
Follow-up: At 4 and 12 weeks: urodynamics, voiding diary, flexible cystoscopy and 3 bladder biopsies, QoL questionnaires.
At 3 months patients are unblinded. Those that received placebo will be offered Botulinum toxin treatment.
Follow-up will be extended to confirm longevity of treatment. A further follow-up time point of 6 months will be instigated collecting the same data as at 4 and 12 weeks.

Intervention Type
Drug

Phase

Not Specified

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

Primary outcome measure
1. Urinary frequency/24 hours
2. Maximum cystometric capacity

Secondary outcome measures
1. Urinary urgency/24 hours
2. Urge incontinence/24 hours
3. QoL: 3 validated QoL questionnaires (KHQ, UDI6, IIQ7)
4. Urodynamic variables:
4.1. time to first invluntary detrusor contraction
4.2. maximum detrusor pressure on filling/voiding
4.3. post void residual

Overall study start date
01/05/2004

Completion date
31/03/2006

Eligibility

Key inclusion criteria
1. Refractory to traditional anticholinergic therapy either due to poor efficacy or side effects
2. Proven detrusor overactivity on urodynamic studies
3. Detrusor overactivity of non-neurogenic origin

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Pregnancy or planned pregnancy
2. Breast Feeding
3. Indwelling catheter
4. Current anticoagulation e.g. heparin or warfarin

5. Neurogenic detrusor overactivity
6. Painful bladder syndromes
7. Previous bladder surgery e.g. augmentation cystoplasty

Date of first enrolment
01/05/2004

Date of final enrolment
31/03/2006

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 Foundation Trust (UK)

Sponsor details
Guy's Hospital
St Thomas' Street
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
British Urological Foundation (UK)

Funder Name
Allergan Ltd. (UK) - Unrestricted educational grany

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	01/06/2009		Yes	No