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Randomised trial of detrusor botulinum toxin injection compared to placebo in idiopathic detrusor overactivity

Submission date	Recruitment status	[X] Prospectively registered
11/04/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/05/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2013	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

Clinical Trials Information System (CTIS)
2004-002981-39

Protocol serial number
UHL 9735 and

Study information

Scientific Title

Acronym
RELAX

Study objectives
The principal research objectives for this trial are:
1. To determine the efficacy of detrusor muscle botulinum toxin A (BOTOX®) injection at relieving symptoms of detrusor overactivity
2. To examine the side effects and complications of detrusor muscle BOTOX® injection
3. To collect basic cost effectiveness data including EuroQol 5D data to allow simple cost effectiveness calculations to be done

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Detrusor overactivity

Interventions
Prior to 16/03/10:
Women will be randomised to receive either a single treatment with 200 IU of botulinum toxin A (BOTOX®) into the detrusor muscle (10 units in 1 ml in 20 separate sites, sparing the trigone), or a single treatment of injection of normal saline (placebo) (20 separate injections of 1 ml) into the detrusor muscle.

Modified 16/03/10:
Women will be randomised to receive either a single treatment with 200 IU of botulinum toxin A (BOTOX®) into the detrusor muscle (10 units in 1 ml in 20 separate sites, sparing the trigone), or a single treatment of injection of placebo (injection vehicle) into the detrusor muscle.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
Diary recorded urinary voiding frequency per 24 hours measured at 6 months. A minimum of two complete diary days will be accepted as valid data. A window of 2 to +8 weeks around the 6 month follow up visit will be allowed.

Key secondary outcome(s)
a. Diary measures
1. Urgency episode frequency/24 hours at 3 and 6 months
2. Incontinence episode frequency at 3 and 6 months
3. Urgency severity assessed by IUSS26 at 3 and 6 months

b. Questionnaire measures
1. International Consultation on Incontinence Questionnaire short form score (ICIQ-SF)
2. Incontinence Quality of Life (IQOL) questionnaire score

c. Physical measures
1. Incidence of complications (including voiding dysfunction, urinary tract infection, haematuria, dysuria, reported muscle weakness)
2. Need for additional treatment during follow up, defined as a new prescription for drugs, or a new referral for other therapies
3. Interval between treatment and patient reported return of troublesome symptoms

d. Health economics
1. EuroQol 5D data compared between baseline, 6 weeks and 6 months follow up
2. Estimated costs of each treatment, using reported health care contacts at 6 weeks and 6 months

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. 8 weeks of continued treatment with oral anticholinergic medication, with a screening Patient Global Impression of Improvement (PGI-I) scale score of 'a little better' or 'worse'. This point of the scale represents a reduction of incontinence episode frequency of around 50% (Slack, unpublished data).
2. 8 weeks of continued treatment, with a verbal response that the treatment has not provided acceptable improvement
3. Treatment stopped because of side effects within 8 weeks
4. Previous treatments stopped because of lack of efficacy, and currently receiving no treatment

Additionally, patients will report at least 8 voids per 24 hours, with at least 2 urgency episodes per 24 hours. Urgency episodes will be defined as those rated as 'moderate' or higher on the Urgency severity scale, and urge incontinence episodes will be defined as recorded leakage in association with an urgency episode.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients with known multiple sclerosis, stroke, spinal injury, or other neurological disease
2. Patients with pre-existing voiding dysfunction (flow rate less than 5th centile, or post void residual volume greater than 100 ml)
3. Patients fulfilling the exclusion criteria for the licensed indications of botulinum toxin (myasethenia gravis and Eaton Lambert syndrome, or allergy to constituents of BOTOX® injection)
4. Patients with co-existing urodynamic stress incontinence

Date of first enrolment
01/02/2006

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Robert Kilpatrick Clinical Sciences Building
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
Moulton Charitable Trust (UK)

Funder Name
Added 16./03/10: Wellbeing of Women (UK)

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	01/09/2012		Yes	No
Results article	results	01/01/2013		Yes	No