

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

Submission date 11/04/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 26/05/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/02/2013	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
UHL 9735 and 2004-002981-39

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

Study design

Randomised controlled trial

Primary study design

Interventional

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 (myasthenia 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