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Trigonal versus trigone-sparing intradetrusor injection of Botulinum Toxin-A for idiopathic detrusor overactivity

Submission date	Recruitment status	[_] Prospectively registered
12/09/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/10/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2010	Urological and Genital Diseases	[_] Record updated in last year

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
N/A

Study information

Scientific Title
Prospective randomised controlled trial comparing trigonal versus trigone-sparing intradetrusor injection of botulinum toxin-a for refractory idiopathic detrusor overactivity

Study objectives
Trigonal injections result in a better outcome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint Hospitals Research Ethics Committee, Adelaide and Meath Hospital, Dublin approved on the 23rd October 2008 (ref: 2008/08/13)

Study design
Interventional randomised controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Idiopathic detrusor overactivity

Interventions
Patients will be randomised to receive intradetrusor injections of 500u Botulinum Toxin-A (Dysport) sparing the trigone or including the trigone. 500u Dysport will be reconstituted with 20ml 0.9% saline. For trigone-sparing patients, 1 ml will be injected into 20 sites around the bladder sparing the trigone. For trigone-including patients, five 1 ml injections will be administered into the trigone and 15 injections around the bladder outside the trigone.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Overactive Bladder Symptom Score (OABSS) Questionnaire Total Score at baseline and at 6 weeks after injection (score range 7-28)

Key secondary outcome(s))
1. OABSS Questionnaire Total Score are 12 and 26 weeks (score range 7-28)
2. OABSS urgency subscale score at 6, 12 and 26 weeks (score range 4-16)
3. Urodynamic parameters at baseline and at 6 weeks
4. Specifically maximum detrusor pressure
5. Maximum cystometric capacity
6. Volume at first desire to void
7. Volume at urgent desire to void
8. Post void residual volume
9. Time to symptom recurrence

Completion date
15/11/2010

Eligibility

Key inclusion criteria
1. Male and female patients, 17 years and over
2. Urodynamic-confirmed detrusor overactivity
3. Have failed greater than or equal to 6 weeks anticholinergic therapy or discontinued therapy due to intolerability

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with any neurological condition or coagulopathies
2. Men with clinical or urodynamic evidence of bladder outflow obstruction
3. Patients with active urinary tract infection
4. Women with positive pregnancy test

Date of first enrolment
15/09/2010

Date of final enrolment
15/11/2010

Locations

Countries of recruitment
Ireland

Study participating centre
c/o Marjorie White-Flynn
Dublin
Ireland
24

Sponsor information

Organisation
Adelaide and Meath Hospital (Ireland)

ROR
https://ror.org/01fvmtt37

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Adelaide and Meath Hospital, Dublin (Ireland) - internal funding

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes