

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

Submission date 12/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/10/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/10/2010	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Rustom Manecksha

Contact details

c/o Marjorie White-Flynn
Lane Ward
Adelaide & Meath Hospital
Dublin
Ireland
24

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

1. OABSS Questionnaire Total Score at 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

Overall study start date

15/09/2010

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

Age group

Adult

Sex

Both

Target number of participants

22

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)

Sponsor details

Department of Urology

Dublin

Ireland

24

Sponsor type

Hospital/treatment centre

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

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