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Fesoterodine fumarate for the treatment of neurogenic bladder

Submission date
24/05/2016

Recruitment status
No longer recruiting

Registration date
02/06/2016

Overall study status
Completed

Last Edited
18/08/2022

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An overactive bladder is a common condition in which the bladder muscle contracts too often or without warning. This causes the sufferer to feel the need to urinate more frequently and/or urgently, the need to get up in the night to urinate and in some cases, incontinence. Neurogenic detrusor overactivity (NDO) is where the overactive bladder has an underlying neurological (nervous system) cause. NDO is most commonly seen in people with multiple sclerosis (MS) or a spinal cord injury (SCI). This happens because changes and damage to the nerves involved in bladder activity can lead to involuntary contractions of the bladder muscle leading to urinary leaking. Fesoterodine is a medication which is used to treat overactive bladder. It works by blocking a chemical in the body which triggers the contractions of the bladder, causing the bladder muscle to relax. The aim of this study is to test the safety and efficiency of using Fesoterodine to treat patients with NDO.

Who can participate?
Adults with an overactive bladder as a result of MS or SCI.

What does the study involve?
After a period of two weeks in which no medication is taken (washout period), all participants receive 8mg Fesoterodine to take every day for three months. At the start of the study and again after the three months of treatment, participants undergo a test in order to find out how well their bladder is working. The test begins with the patient emptying their bladder into a special toilet to measure the amount of urine passed and the flow. Two very thin tubes (catheters) are then placed inside the bladder in order to monitor how it fills up (one tube fills up the bladder with liquid and the other measures the pressure). Once the bladder is full, x rays are taken, before the patient is asked to empty the bladder into the special toilet again with the tubes in place.

What are the possible benefits and risks of participating?
Participants benefit from receiving an in depth evaluation of how well their bladder is working, as well as receiving a treatment likely to help improve their bladder function and quality of life. There are no notable risks involved for participants in this study.

Where is the study run from?
National Rehabilitation Center, Athens (Greece)

When is the study starting and how long is it expected to run for?
March 2015 to March 2018

Who is funding the study?
National Rehabilitation Center, Athens (Greece)

Who is the main contact?
Dr Charalampos Konstantinidis

Contact information

Type(s)
Scientific

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13122

Additional identifiers

Protocol serial number
2287/23-3-2015

Study information

Scientific Title
Efficacy and safety of fesoterodine fumarate in neurogenic detrusor overactivity due to spinal cord lesion (SCL) or multiple sclerosis (MS)

Study objectives
The aim of this study is to determine the safety and the efficacy of the use of Fesoterodine fumarate for the treatment of patients suffering from neurogenic detrusor overactivity (NDO).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Scientific Committee of National Rehabilitation Center, 30/11/2015, ref: 9/9-12-2015

Study design
Open label prospective non-randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neurogenic detrusor overactivity (NDO)

Interventions
There will be a 2 week wash-out period prior to enrollment for patients under drug medication for the treatment of NDO. All patients will undergo a first confirmatory baseline UDS, completing simultaneously a 3 days bladder diary, and the SF-Qualiveen as a QoL questionnaire. Afterwards, all subjects will receive 8 mg Fesoterodine daily for 3 months. At the completion of this period they will undergo a second UDS completing also a second bladder diary and the SF-Qualiveen. Each UDS will be performed with the same equipment at the same environment from the same clinician, unaware of the study hypothesis, according to ICS' standard good urodynamics practices and terms.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Fesoterodine fumarate

Primary outcome(s)
Bladder function will be evaluated using Urodynamics Testing (UDS), a three day bladder diary and the SF-Qualiveen questionnaire at baseline and three months.

Key secondary outcome(s))
No secondary outcome measures.

Completion date
27/03/2018

Eligibility

Key inclusion criteria
1. Aged between 18-80 years old
2. Suffering from neurogenic detrusor overactivity, confirmed by urodynamics testing, secondary to MS or SCI of at least 6 months prior to enrollment
3. Patients suffering from MS should be clinically stable for at least 3 months prior to enrollment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. UTI
2. History of urothelial cancer
3. Urolithiasis
4. Stress incontinence
5. Interstitial cystitis
6. Pelvic organ prolapsed (≥ III grade)
7. Prior pelvic surgery or pelvic radiation treatment
8. Uncontrolled narrow angle glaucoma
9. Pregnancy
10. Dementia

Date of first enrolment
10/12/2015

Date of final enrolment
10/12/2017

Locations

Countries of recruitment
Greece

Study participating centre
National Rehabilitation Center
Chasias Avenue
8th bus stop & Spirou Theologou 1
Ilion

Athens
Greece
13122

Sponsor information

Organisation
National Rehabilitation Center

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Rehabilitation Center, Greece

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/09/2021	02/03/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			18/08/2022	No	No