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Pathophysiology of urge incontinence in older women

Submission date	Recruitment status	[_] Prospectively registered
09/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/07/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/07/2006	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
1999P-001891

Study information

Scientific Title

Study objectives
Older adults with urge incontinence respond well to generic oxybutynin when it is titrated for physiological differences in older patients. This treatment approach is efficacious even in detrusor hyperreflexia with impaired contractility (DHIC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Brigham and Women's Hospital Institutional Review Board (IRB) on 26/09/1995, protocol number 94-6641-01

Study design
Double-blind, randomized, placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urge incontinence, detrusor hyperreflexia with impaired contractility (DHIC)

Interventions
1. Immediate release oxybutynin following treatment of reversible causes, dose titrated for four weeks and maintained for further four weeks
2. Control group: placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Oxybutynin

Primary outcome(s)
Percentage reduction in incontinence episodes on 4-day bladder diary

Key secondary outcome(s))
1. Number of subjects dry at end of study
2. Subjective satisfaction

Completion date
31/03/2006

Eligibility

Key inclusion criteria
Cognitively intact, community-dwelling persons at least 55 years old with urge incontinence at least every two days

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
Female

Key exclusion criteria
1. Significant stress incontinence
2. Outlet obstruction
3. Post-voiding residual (PVR) urine >300 ml
4. Mini mental state examination (MMSE) <24/30
5. Inability to go to the toilet independently
6. Contraindication to antimuscarinic therapy
7. Gastrointestinal obstruction
8. Megacolon
9. Severe liver or renal disease
10. Uncontrolled hyperthyroidism
11. Multiple sclerosis
12. Anteroposterior resection
13. Pelvic radiation
14. Spinal cord disease resulting in para- or quadri-plegia

Date of first enrolment
01/03/1996

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
United States of America

Study participating centre
Suite 500
Pennsylvania
United States of America
15213

Sponsor information

Organisation
National Institutes of Health (USA)

ROR
https://ror.org/01cwqze88

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (NIH) (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK])

Alternative Name(s)
US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary