

# Pathophysiology of urge incontinence in older women

|                                        |                                                              |                                                      |
|----------------------------------------|--------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>09/03/2006   | <b>Recruitment status</b><br>No longer recruiting            | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                              | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>03/07/2006 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                              | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>03/07/2006       | <b>Condition category</b><br>Urological and Genital Diseases | <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**  
Dr Neil Resnick

**Contact details**  
Suite 500  
Kaufmann Medical Building  
Pittsburgh  
Pennsylvania  
United States of America  
15213  
+1 412 692 2360  
ResnickNM@dom.pitt.edu

## 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

**Primary study design**

Interventional

**Study design**

Double-blind, randomized, placebo-controlled trial

**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