

Pathophysiology of urge incontinence in older women

Submission date 09/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/07/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 03/07/2006	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Percentage reduction in incontinence episodes on 4-day bladder diary

Secondary outcome measures

1. Number of subjects dry at end of study
2. Subjective satisfaction

Overall study start date

01/03/1996

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

Age group

Senior

Sex

Female

Target number of participants

250

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)

Sponsor details

9000 Rockville Pike

Bethesda

Maryland

United States of America

20892

Sponsor type

Government

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)

Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

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