

# Evaluation of the efficacy of oxybutynin and imipramine in the management of detrusor instability

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/11/2015	<b>Condition category</b> 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

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## Additional identifiers

**Protocol serial number**  
G9410491

## Study information

**Scientific Title**  
Evaluation of the efficacy of oxybutynin and imipramine in the management of detrusor instability

**Study objectives**

To investigate the efficacies of oxybutynin and imipramine in the treatment of detrusor instability. A pragmatic trial titrating dose against effect and side effects. All patients continuing with bladder education.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Not Specified

**Health condition(s) or problem(s) studied**

Incontinence

**Interventions**

1. Oxybutynin: Oxybutynin titrated to a maximum dose of 5 mg tds and imipramin placebo
2. Imipramine: Imipramine titrated to a maximum dose of 75 mg bd and Oxybutynin placebo
3. Control: matching placebo tablets of Imipramine and Oxybutynin

**Intervention Type**

Drug

**Phase**

Not Specified

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

oxybutynin and imipramine

**Primary outcome(s)**

Clinical assessment using urinary diaries and 24 hour home pad tests.

**Key secondary outcome(s))**

Not provided at time of registration

**Completion date**

01/09/2001

**Eligibility****Key inclusion criteria**

1. Failed conservative therapies for urinary dysfunction (nursing interventions)
2. Urodynamically proven detrusor instability

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Key exclusion criteria**

1. Pregnancy
2. Malignancy
3. Fistula
4. Contra-indications to the use of oxybutynin or imipramine
5. Bladder outflow obstruction (measured urodynamically)

**Date of first enrolment**

01/06/1997

**Date of final enrolment**

01/09/2001

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Department of Epidemiology and Public Health

Leicester

United Kingdom

LE1 2TP

**Sponsor information**

Organisation

Medical Research Council (MRC) (UK)

## **Funder(s)**

### **Funder type**

Research council

### **Funder Name**

Medical Research Council (MRC) (UK)

### **Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### **Location**

United Kingdom

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

#### **IPD sharing plan summary**

Not provided at time of registration