

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

**Submission date**

25/10/2000

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

25/10/2000

**Overall study status**

Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**

17/11/2015

**Condition category**

Urological and Genital Diseases

☐ Individual participant data

☐ Record updated in last year

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/06/1997

**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

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

345

**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**

England

United Kingdom

**Study participating centre**

**Department of Epidemiology and Public Health**

Leicester

United Kingdom

LE1 2TP

## **Sponsor information**

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

20 Park Crescent

London

United Kingdom

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+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

**Sponsor type**

Research council

**Website**

<http://www.mrc.ac.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, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **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