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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 17/11/2015	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr C McGrother

Contact details
Department of Epidemiology and Public Health
University of Leicester
22-28 Princess Road West
Leicester
United Kingdom
LE1 2TP

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. Urodynamicaly 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
W1B 1AL
+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