

A randomised, double blind, placebo controlled, crossover trial of the adjuvant properties of imipramine for the overactive bladder

Submission date 13/02/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/06/2016	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

Prof James Malone Lee

Contact details

Department of Medicine
University College London
Clerkenwell Building
Highgate Hill
Archway
London
United Kingdom
N19 5LW
+44 (0)207 2885301
james.malone-lee@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PB-PG-0107-12198

Study information

Scientific Title

A randomised, double blind, placebo controlled, crossover trial of the adjuvant properties of imipramine for the overactive bladder

Study objectives

We hypothesise that 25 mg imipramine in addition to antimuscarinic drugs is superior to placebo in addition to an antimuscarinic drug for the treatment of overactive bladder symptoms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

An application to the Moorfields and Whittington Research Ethics Committee is in progress as of 13/02/2008 – approval pending

Study design

Randomised double-blind placebo-controlled cross-over trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Overactive bladder symptoms

Interventions

Imipramine 25 mg once a day given orally vs placebo.

Imipramine will be given for 6 weeks followed by placebo for 6 weeks and vice versa in the other arm of this cross-over trial.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Imipramine

Primary outcome measure

Urgency score questionnaire (Al Buheissi S, et al., 2008), carried out after 1 week of run-in period and at 2, 4, 6, 8, 10 and 12 weeks.

Secondary outcome measures

The following will be assessed after 1 week of run-in period and at 6 and 12 weeks:

1. 24 hour urinary frequency
2. Daily urinary Incontinence records
3. Patient preference for treatment
4. Incontinence Quality of Life questionnaire (I-QOL) score
5. Record of side effects

Overall study start date

01/05/2008

Completion date

01/05/2010

Eligibility**Key inclusion criteria**

1. Age \geq 18 years
2. Able to consent
3. Suffering from overactive bladder symptoms
4. Taking antimuscarinic treatment for detrusor overactivity

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Unable to consent
2. Pregnant
3. Breast feeding
4. Recent myocardial infarction
5. History of psychiatric illness
6. Taking monoamine oxidase inhibitors
7. <18 years

Date of first enrolment

01/05/2008

Date of final enrolment

01/05/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University College London

London

United Kingdom

N19 5LW

Sponsor information

Organisation

The Whittington Hospital NHS Trust (UK)

Sponsor details

Magdala Avenue

London

England

United Kingdom

N19 5LW

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Senga.Steel@whittington.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.whittington.nhs.uk>

ROR

<https://ror.org/01ckbq028>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research - the Research for Patient Benefit (RfPB) programme (ref: PB-PG-0107-12198)

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