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

Submission date	Recruitment status	[X] Prospectively registered
13/02/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2016	Urological and Genital Diseases	[_] 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

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 >= 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
-
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