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A randomised, double-blind validation of the significance of occult pyuria for the symptoms of the overactive bladder

Submission date 04/06/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/08/2007	**Overall study status** Completed	
Last Edited 07/06/2017	**Condition category** Urological and Genital Diseases	

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
OAB/AB/07

Study information

Scientific Title
A randomised, double-blind validation of the significance of occult pyuria for the symptoms of the overactive bladder

Acronym
NOD (Nitrofurantoin in Overactive Detrusor)

Study objectives
Study hypothesis amended as of 11/09/2007:
The aim of this study is to determine whether treatment with nitrofurantoin improves total 24 hour incontinence episodes in patients presenting with symptoms of overactive bladder, who have significant numbers of inflammatory cells in their urine but a negative urine culture.

Study hypothesis provided at time of registration:
The aim of this study is to determine whether treatment with pivmecillinam improves total 24 hour incontinence episodes in patients presenting with symptoms of overactive bladder, who have significant numbers of inflammatory cells in their urine but a negative urine culture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Whittington and Moorfields Research Ethics Committee, 07/05/2008, ref: 08/H0721/23

Study design
Randomised placebo-controlled double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Overactive bladder

Interventions

Interventions amended as of 23/11/2007:
Intervention group: Nitrofurantoin (Brand Name: Macrodantin®) 100 mg orally b.d (twice daily) for 6 weeks
Control group: Placebo administered orally, twice daily for 6 weeks

Please note that this change is due to difficulty in finding suitable placebo for the pivmecillinam preparation.

Interventions provided at time of registration:
Intervention group: Pivmecillinam will be administered orally at a dose of 400 mg twice daily
Control group: Placebo administered orally, twice daily

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Number of incontinence episodes per 24 hours, assessed by bladder diary chart recorded by the patients during the intervention

Secondary outcome measures
Secondary outcome measure amended as of 11/09/2007:
1. To determine whether treatment with nitrofurantoin improves other symptoms of over active bladder, the following will be assessed:
1.1. 24-urinary frequency
1.2. Urgency score assessed at 2 weekly intervals until the end of the trial at 6 weeks
1.3. Average voided volume assessed at 2 weekly intervals until the end of the trial at 6 weeks
1.4. Quality of life (I-Qol) assessed at 2 weekly intervals until the end of the trial at 6 weeks
2. Assessment to determine whether pus cells are eliminated from the urine, <10 WBC/uL, after long-term treatment with nitrofurantoin. This will be measured at 2 weekly intervals until the end of the trial at 6 weeks
3. Recording side effects of treatment

Secondary outcome measures provided at time of registration:
1. To determine whether treatment with Pivmecillinam improves other symptoms of over active bladder, the following will be assessed:
1.1. 24-urinary frequency
1.2. Urgency score assessed at 2 weekly intervals until the end of the trial at 6 weeks
1.3. Average voided volume assessed at 2 weekly intervals until the end of the trial at 6 weeks
1.4. Quality of life (I-Qol) assessed at 2 weekly intervals until the end of the trial at 6 weeks
2. Assessment to determine whether pus cells are eliminated from the urine, <10 WBC/uL, after long-term treatment with Pivmecillinam. This will be measured at 2 weekly intervals until the end of the trial at 6 weeks
3. Recording side effects of treatment

Overall study start date

01/10/2007

Completion date
01/10/2008

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Both males and females
3. Symptoms of frequency more than or equal to 8 per day; urgency with or without urge incontinence
4. Able to complete a bladder diary chart for at least three days in one week
5. Able to complete a symptom questionnaire

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 in each arm

Key exclusion criteria
1. Age less than 18 years
2. Inability to consent
3. Bactiuria of >105 Colony Forming Unit (CFU) /ml identified by conventional Midstream Urine Specimen (MSU) culture
4. Negative urine microscopy identified by <10 White Blood Cells (WBC)/uL on a fresh, unspun sample of urine

Date of first enrolment
01/10/2007

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Archway Campus
London
United Kingdom
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Sponsor information

Organisation
The Whittington Hospital NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ckbq028

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Whittington Hospital NHS Trust (UK)

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