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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Prof James Malone-Lee

#### Contact details

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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

#### 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 N19 5LW

# Sponsor information

## Organisation

The Whittington Hospital NHS Trust (UK)

#### Sponsor details

Magdala Avenue Highgate Hill London England United Kingdom N19 5LW +44 (0)207 288 5269 james.malone-lee@ucl.ac.uk

#### 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