

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

<b>Submission date</b> 04/06/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/06/2017	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Overactive bladder

### **Interventions**

Interventions amended as of 23/11/2007:

Intervention group: Nitrofurantoin (Brand Name: Macrochantin®) 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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Age less than 18 years
2. Inability to consent
3. Bactiuria of >10<sup>5</sup> 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**

United Kingdom

England

**Study participating centre**

**Archway Campus**

London

United Kingdom

N19 5LW

**Sponsor information****Organisation**

The Whittington Hospital NHS Trust (UK)

ROR

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

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

The Whittington Hospital NHS Trust (UK)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

#### **IPD sharing plan summary**

Not provided at time of registration