

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	☒ Prospectively registered
Registration date 21/08/2007	Overall study status Completed	☐ Protocol
Last Edited 07/06/2017	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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
Clerkenwell Building
Archway Campus
Highgate Hill
London
United Kingdom
N19 5LW

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

Primary study design

Interventional

Study design

Randomised placebo-controlled double-blind trial

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 >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**

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