

# Development and randomised controlled trial of dipsticks and diagnostic algorithms for the management of urinary tract infection

**Submission date**

25/04/2003

**Recruitment status**

No longer recruiting

Prospectively registered

Protocol

**Registration date**

25/04/2003

**Overall study status**

Completed

Statistical analysis plan

Results

**Last Edited**

26/02/2010

**Condition category**

Urological and Genital Diseases

Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Paul S Little

**Contact details**

Primary Medical Care Group  
Community Clinical Sciences Division  
University of Southampton  
Aldermoor Health Centre  
Aldermoor Close  
Southampton  
United Kingdom  
SO16 5ST  
+44 (0)23 8024 1062  
psl3@soton.ac.uk

## Additional identifiers

**Protocol serial number**

HTA 97/14/06

## Study information

## Scientific Title

### Study objectives

1. To develop and test the use of different algorithms/symptom scores in the diagnosis of urinary tract infection (UTI)
2. To develop and test the use of different dipstick strategies in the diagnosis of UTI
3. To assess the cost effectiveness of common management strategies in the diagnosis and treatment of UTI
4. To assess the effect of the different strategies on patient satisfaction, beliefs and behaviour

Two phases:

1. Dipstick and score validation
2. Block randomised open trial of management strategies

More details can be found at: <http://www.hta.ac.uk/1205>

Protocol can be found at: <http://www.hta.ac.uk/protocols/199700140006.pdf>

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Primary study design

Interventional

### Study design

Randomised controlled trial

### Study type(s)

Treatment

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

Urinary tract infection

### Interventions

Phase 1. Different symptom scores (naive Bayesian, adjusted Bayesian, symptom counts) and combinations of dipstick results will be developed to predict 'standard' monosodium urate (MSU) diagnosis in half the subjects (randomly chosen). The optimal strategies will be determined - from sensitivity, specificity, predictive values, likelihood ratios, and workload implications from the R.O. curves and tested with previous scores in the other half of the data. Phase 2. This will be preceded by a development phase to determine the feasibility of trial procedures and exact strategy for each group derived from the results of phase 1. Patients will be block randomised to five groups:

1. Empiric antibiotic treatment (3 day course of trimethoprim)
2. Treatment based on algorithm/score (from phase 1)
3. Treatment based on dipstick (based on phase 1)
4. Treatment based on positive MSU examination and culture
5. Control group (symptomatic treatment based on alkalinization of urine and other symptomatic measures)

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Symptom diary
2. Satisfaction
3. Belief in antibiotics
4. Notes review for
  - 4.1. reattendance
  - 4.2. complications
  - 4.3. referral
5. Costs
  - 5.1. manual timing for GP and other staff costs
  - 5.2. marginal costs in processing the MSUs

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

09/09/2006

**Eligibility****Key inclusion criteria**

Subjects presenting with suspected urinary tract infections (UTI)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

Pregnant women and women over the age of 75

**Date of first enrolment**

10/09/2001

**Date of final enrolment**

09/09/2006

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

**Primary Medical Care Group**

Southampton

United Kingdom

SO16 5ST

## Sponsor information

### Organisation

Department of Health (UK)

### ROR

<https://ror.org/03sbpja79>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type

Details  
results

Date created

Date added

Peer reviewed?

Patient-facing?

<a href="#">Results article</a>		01/08/2006	Yes	No
<a href="#">Results article</a>	results	05/02/2010	Yes	No
<a href="#">Other publications</a>	cost effectiveness analysis	05/02/2010	Yes	No