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

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/02/2010	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

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
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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	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article		01/08/2006	Yes	No
Results article	results	05/02/2010	Yes	No
Other publications	cost effectiveness analysis	05/02/2010	Yes	No