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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

Registration date
25/04/2003

Overall study status
Completed

Last Edited
26/02/2010

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/09/2001

Completion date
09/09/2006

Eligibility

Key inclusion criteria
Subjects presenting with suspected urinary tract infections (UTI)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
309 (added 09/02/10; see publication)

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
England

United Kingdom

Study participating centre
Primary Medical Care Group
Southampton
United Kingdom
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Sponsor information

Organisation
Department of Health (UK)

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2006		Yes	No
Other publications	cost effectiveness analysis	05/02/2010		Yes	No
Results article	results	05/02/2010		Yes	No