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PRImary care Streptococcal Management study (PRISM) Rapid tests for streptococcal sore throat

Submission date	Recruitment status	[_] Prospectively registered
13/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/01/2014	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.prismstudy.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 05/10/01

Study information

Scientific Title

Acronym
PRISM

Study objectives
1. To assess which Rapid streptococcal antigen detection test (RADT) is the most accurate in predicting the presence of group A streptococcus by throat swab in a clinical sample from primary care
2. To estimate the error from sampling bias by performing parallel standardised in vitro studies
3. To assess the validity of a scoring system based on the throat swab as the reference standard (such as the Centor criteria) in a UK population
4. To assess the effectiveness and cost-effectiveness of rapid tests when compared to clinical scoring rules and delayed antibiotic prescription
5. To explore the effect of additional benefit from the RADT use on GP diagnostic prediction accuracy and treatment decisions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West hampshire REC, MREC number: 06/Q1702/111

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Diagnostic

Participant information sheet
Find information pertinent to closest recruitment site at: http://www.prismstudy.org /Study_Documents/default.htm

Health condition(s) or problem(s) studied
Lower Respiratory Tract Infections (LRTI)

Interventions
This study is in two phases:
Phase I is a validation and development phase and will include five components:
1. A clinical study to determine the ease of use and overall performance in clinical settings of the 5 currently available RADTs using the throat swab as the reference standard
2. Nested data from the same sample will be used to assess whether the a scoring system based on the throat swab as a reference standard (such as the Centor criteria) requires modification
3. In vitro studies to assess the performance of RADTs in standardised conditions and thus assess the issue of sampling bias when using RADTs
4. A qualitative study to explore patients and GPs perceptions about the use of RADTs

Phase II. This trial will compare management using a) the best RADT defined from phase 1 compared with b) a clinical scoring rule (a Centor-like criteria based on predicting the results of throat swabs) and c) with the empirical strategy of delayed antibiotic prescription. Phase II will include a cost consequences analysis, which along with a review of the longer term effects of reduced antibiotic resistance will feed into a simple cost effectiveness model.

Phase I. RADTs: in adults two double throat swabs will be taken (allowing four tests for each adult), and in children only one double swab (due to multiple swabs being less acceptable in children). Each swab will be used for both conventional microbiology (culture and sensitivity) and for one of five randomly chosen rapid tests (piloting has shown this is feasible and minimises sampling variation). We will assess currently available RADTs (Streptatest; OSOM Ultra Strep A; Quickvue; Clearview Exact Test; and IMI Test Pack plus Strep A). Variation in performance due to sampling bias will be assessed by in vitro studies, using standard antigen loads of three group A streps and controls. The choice of RADT for phase II will take account of the best clinical study results, the in vitro results, and ease of use.

Phase II. Patients will be individually randomised using a web based service to three groups, stratified by physician belief in the likelihood of bacterial infection: 1) RADT use 2) Clinical scoring rule 3) Delayed prescribing. The RADT used, and the optimal strategy for use, will be identified from Phase I. The clinical score will be the Centor criteria (3 out of 4 criteria present), or the alternative clinical rule developed from phase I . Delayed prescribing will involve antibiotics to be used/collected after 3-5 days if symptoms are worsening or not starting to settle.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Phase 1: Ease of use and performance in clinical setting of 5 RADTs
Phase 2: Diary scores; duration of illness

Secondary outcome measures
Phase 2:
1. Antibiotic use

2. Side effects
3. Medicalistion of illness

Overall study start date
01/10/2006

Completion date
30/09/2010

Eligibility

Key inclusion criteria
Phase 1: Adults/children aged 5 and over presenting with acute sore throat (2 weeks or less; and with some abnormality of examination of the throat i.e. erythema and/or pus).
Phase 2: . Previously well subjects aged 3 years and over with acute illness (2 weeks or less), presenting with sore throat as the main symptom, with an abnormal examination of the pharynx.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Phase 1: 438 -1176; Phase 2: 850

Key exclusion criteria
Phase 1:
1. Other non infective causes of sore throat (e.g. apthous ulceration, candida, drugs)
2. Unable to consent (e.g. dementia, uncontrolled psychosis)
Phase 2:
1. Quinsy, previous rheumatic fever, glomerulonephritis.
2. Serious chronic disorders where antibiotics are needed (e.g. cystic fibrosis, valvular heart disease), or mental health problems (e.g. learning difficulties - unable to complete outcome measures).

Date of first enrolment
01/10/2006

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Medical Care
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

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	10/10/2013		Yes	No
Results article	results	01/01/2014		Yes	No