

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

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| <b>Submission date</b><br>13/02/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>27/02/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>31/01/2014       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data  |

**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](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. Medicalisation 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. aphthous 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**

Southampton

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## **Sponsor information**

**Organisation**

University of Southampton (UK)

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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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 10/10/2013   |            | Yes            | No              |
| <a href="#">Results article</a> | results | 01/01/2014   |            | Yes            | No              |