

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Paul Little

**Contact details**  
Primary Medical Care  
Aldermoor Health Centre  
Aldermoor Close  
Southampton  
United Kingdom  
SO16 5ST  
+44 (0)23 80241062  
psl3@soton.ac.uk

## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Diagnostic

## **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(s)**

Phase 1: Ease of use and performance in clinical setting of 5 RADTs

Phase 2: Diary scores; duration of illness

### **Key secondary outcome(s)**

Phase 2:

1. Antibiotic use
2. Side effects
3. Medicalisation of illness

### **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

### **Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Primary Medical Care

Southampton

United Kingdom

SO16 5ST

**Sponsor information****Organisation**

University of Southampton (UK)

**ROR**

<https://ror.org/01ryk1543>

# 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?
<a href="#">Results article</a>	results	10/10/2013		Yes	No
<a href="#">Results article</a>	results	01/01/2014		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes