A study to assess novel approaches to antibiotic prescription for sore throat

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date 23/01/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
11/12/2008	Infections and Infestations			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - Little

Contact details

University of Southampton Aldermoor Health Centre Southampton United Kingdom SO16 5ST

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers T2.50.93

Study information

Scientific Title

Study objectives

To evaluate three pragmatic treatment options currently in use in the general practice management of sore throat, which will incorporate a patient centred advice package developed during the project. This will be addressed in three phases:

Phase 1 - to assess the concerns of the patients presenting with sore throat, and develop standard advice which addresses these concerns

Phase 2 - to assess the acceptability, symptom control and complications of three different approaches to prescribing in sore throat.

Phase 3 (principal aim) - to assess the long term outcome (patient worries, surgery attendance, antibiotic prescription, complications) of the three approaches to prescribing.

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)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Infection and infestations: Common cold

Interventions

- 1. Antibiotics and instructions to finish courses (Penicillin V or Erythromycin)
- 2. Advice alone (re symptom control/antibiotic efficacy/natural history/patient concerns)
- 3. Advice plus offering the patient choice of whether to have antibiotics or not

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Duration of symptoms, satisfaction and compliance

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/1994

Completion date

31/08/1996

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Added December 2008: 3714

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/02/1994

Date of final enrolment

31/08/1996

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Southampton

Southampton United Kingdom SO16 5ST

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/03/1997		Yes	No