# Randomised controlled trial of a leaflet and three prescribing strategies for the management of acute lower respiratory tract illness. Acute Cough Trial

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
23/10/2000  Registration date	No longer recruiting  Overall study status	☐ Protocol
		Statistical analysis plan
23/10/2000	Completed	[X] Results
<b>Last Edited</b> 30/07/2009	Condition category Respiratory	[] Individual participant data

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Paul S Little

#### Contact details

Primary Medical Care Group Community Clinical Sciences Division University of Southampton Aldermoor Health Centre Aldermoor Close Southampton United Kingdom SO16 5ST +44 (0)23 8024 1062 psl3@soton.ac.uk

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

# ClinicalTrials.gov number

# Secondary identifying numbers

G108/322

# Study information

#### Scientific Title

# Acronym

**ACT** 

# Study objectives

- 1. To develop, pilot and assess the pragmatic outcomes of three commonly used management strategies for acute lower respiratory tract illness in primary care
- 2. To determine the effect of an information leaflet
- 3. To assess predictors of poor outcome
- 4. To assess predictors of return to surgery

# 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)

GP practice

# Study type(s)

**Not Specified** 

# Participant information sheet

# Health condition(s) or problem(s) studied

Lower respiratory tract infection

#### **Interventions**

Patients were assigned to one of six groups by a factorial design: leaflet or no leaflet and one of three antibiotic groups (immediate antibiotics, no offer of antibiotics, and delayed antibiotics).

# Intervention Type

Other

#### **Phase**

**Not Specified** 

#### Primary outcome measure

Short term: perception of antibiotic efficacy, intention to consult, symptom resolution, fever

resolution, complication rate, satisfaction with treatment. Long term: return rate to the surgery, admissions, referral.

# Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/05/1998

# Completion date

30/04/2002

# **Eligibility**

# Key inclusion criteria

Patients four years and over presenting with acute cough (less than 21 days) and one or more of: sputum, dyspnoea, wheeze, chest pain

# Participant type(s)

Patient

# Age group

**Not Specified** 

#### Sex

Both

# Target number of participants

1100

#### Key exclusion criteria

Main exclusions are pneumonia, chronic lung disease, asthma, other serious pathology

#### Date of first enrolment

01/05/1998

#### Date of final enrolment

30/04/2002

# Locations

# Countries of recruitment

England

**United Kingdom** 

Study participating centre Primary Medical Care Group Southampton United Kingdom SO16 5ST

# Sponsor information

# Organisation

University of Southampton (UK)

# Sponsor details

University Road Southampton England United Kingdom SO17 1BJ +44 (0)23 8059 5000

# Sponsor type

University/education

#### Website

http://www.soton.ac.uk/

#### **ROR**

https://ror.org/01ryk1543

# Funder(s)

# Funder type

Research council

### Funder Name

Medical Research Council (MRC) (UK)

# Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

# **Funding Body Type**

Government organisation

# **Funding Body Subtype**

National government

# Location

**United Kingdom** 

# **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	22/06/2005		Yes	No