ISRCTN57615270 https://doi.org/10.1186/ISRCTN57615270

Acoustic analysis of the effect of codeine on cough in asthma and chronic obstructive pulmonary disease

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 12/05/2008	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Ashley Woodcock

Contact details
North West Lung Centre
South Manchester University Hospitals NHS Trust
Wythenshawe Hospital
Southmoor Road
Manchester
United Kingdom
M23 9LT
+44 (0)161 291 5873
ashley.woodcock@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0226093097

Study information

Scientific Title

Study objectives
1. To validate cough programme in the clinical setting (both in hospital and in the home environment)
2. To determine the specificity and sensitivity of the technique
3. To develop the programme further using more advanced sound analysis to improve detection and recognition of cough
4. To test the programme's ability to detect the effect of codeine linctus

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Codeine phosphate 60 mg or matched placebo were given, in random order, at the start of each cough recording (0 and 12 hours).

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Codeine

Primary outcome measure
The number of coughs in each group before and after codeine, both in hospital and at home.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2002

Completion date
31/05/2003

Eligibility

Key inclusion criteria
21 patients with physician-diagnosed, stable disease who complained of cough.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
21

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2002

Date of final enrolment
31/05/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North West Lung Centre
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Charity

Funder Name
North West Lung Centre Charity (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	01/04/2006		Yes	No