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Dextromethorphan in smoking related cough

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 27/10/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0084120889

Study information

Scientific Title
A single centre, randomised, double blind, placebo controlled, crossover, pilot study to determine the efficacy and safety of dextromethorphan versus placebo for the treatment of smoking related cough

Study objectives
This project was undertaken to evaluate the efficacy of dextromethorphan in the optimised cough formulation compared to placebo in a group of subjects with smoking related cough.

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
Respiratory: Smoking related cough

Interventions
Dextromethorphan versus placebo.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Reduction in cough frequency measured subjectively after waking on treatment day 1 over time periods 0 - 10, 10 - 20, 20 - 40 and 40 - 60 minutes.

Secondary outcome measures
1. Reduction in cough frequency on days 2 - 5
2. Change in cough symptoms (severity expectoration, chest pain, etc.,) and nocturnal cough
3. Change in cough threshold as measured via citric acid cough challenge

Overall study start date
11/03/2003

Completion date
01/06/2004

Eligibility

Key inclusion criteria
50 volunteers between 18 - 70 years.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
11/03/2003

Date of final enrolment
01/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Academic Department of Medicine
Cottingham, East Yorkshire
United Kingdom
HU16 5JQ

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
Industry

Funder Name
The North and South Bank Research and Development Consortium (NHS R&D Support Funding) (UK)

Funder Name
Procter & Gamble (UK)

Alternative Name(s)
Procter & Gamble, PandG, The Procter & Gamble Company, P&G

Funding Body Type
Government organisation

Funding Body Subtype

For-profit companies (industry)

Location
United States of America

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	01/05/2008		Yes	No