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Dextromethorphan in smoking related cough

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2010	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

Completion date
01/06/2004

Eligibility

Key inclusion criteria
50 volunteers between 18 - 70 years.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (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 and G, 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2008		Yes	No