

Dextromethorphan in smoking related cough

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/10/2010	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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