

Dextromethorphan in smoking related cough

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/10/2010	Condition category Respiratory	☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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