Clinical trial results:
A 2-arm, randomised, single - (investigator) blind, controlled, parallel design study in common cold sufferers experiencing cough and nasal congestion to assess the effects of Vicks® VapoRub® (VVR) on elements of sleep quality

Summary

EudraCT number	2013-004524-11
Trial protocol	GB
Global end of trial date	15 May 2015

Results information

Result version number	v1 (current)
This version publication date	20 November 2016
First version publication date	20 November 2016

Trial information

Trial identification

Sponsor protocol code	2013105

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Procter and Gamble
Sponsor organisation address	Rusham Park, Egham, United Kingdom, TW20 9NW
Public contact	Dr David Hull, Procter and Gamble, +44 1784474408, hull.jd.2@pg.com
Scientific contact	Dr David Hull, Procter and Gamble, +44 1784474408, hull.jd.2@pg.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 April 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 May 2015
Global end of trial reached?	Yes
Global end of trial date	15 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy Objective:

The objective of the study was to investigate the effects of VVR versus petrolatum on subjective and objective sleep measurements in subjects with the common cold.

Protection of trial subjects:

Participants were supervised by appropriately trained and delegated staff throughout their study visits.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 November 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	99
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

100 participants were recruited in the United Kingdom between 05-Nov-2014 and 11-May-2015.

Pre-assignment

Screening details:

Healthy male and female participants, aged 18-65 yrs, suffering from a self-diagnosed common cold of no more than 36 hours' duration.

141 potential participants were screened. There were 20 screen failures and 21 people were pre-screened but never returned with a cold.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Investigator[1]

Blinding implementation details:

Only the Clinical Supplies Department of P&G (Bracknell, UK) and qualified study centre designee(s) responsible for handling the study medications at the site had access to the study medication sequence and codes. The study medication codes were controlled by the Clinical Supplies Department of P&G (Bracknell, UK). The designee(s) were not involved in any other aspects related to the conduct of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Petrolatum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

Sonneborn Refined Products BV, Parsippany, NJ, USA.

Test product was applied at home by the subjects once on each of 2 nights immediately before retiring to bed (7.5 g each night sequentially over the regions of the chest, throat, and back). Additional instructions were provided to ensure that all 7.5 g of product was applied.

Arm title	Active

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Vicks VapoRub
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

Vicks® VapoRub® includes a combination of levomenthol (2.75% w/w), eucalyptus oil (1.5% w/w),

turpentine oil (5% w/w) and camphor (5% w/w) as active ingredients, and thymol, cedarwood oil, and white soft paraffin as excipients.
Test product was applied at home by the subjects once on each of 2 nights immediately before retiring to bed (7.5 g each night sequentially over the regions of the chest, throat, and back). Additional instructions were provided to ensure that all 7.5 g of product was applied.

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Due to the nature of the study products it was not possible for participants to be blinded, however, study investigators interacting with the participants were blinded.

Number of subjects in period 1	Placebo	Active
Started	50	50
Completed	50	49
Not completed	0	1
Lost to follow-up	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Active
Reporting group description: -	

Reporting group values	Placebo	Active	Total
Number of subjects	50	50	100
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	23.7	23.1	
full range (min-max)	18 to 52	18 to 65	-
Gender categorical Units: Subjects			
Female	29	32	61
Male	21	18	39

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Active
Reporting group description: -	

Primary: Subjective Sleep Quality (Visual Analogue Scale)

End point title	Subjective Sleep Quality (Visual Analogue Scale)
End point description: Change from baseline least squares mean (standard error)	
End point type	Primary
End point timeframe: Baseline, Test Period: Day 1 and day 2	

End point values	Placebo	Active		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	46		
Units: mm				
least squares mean (standard error)	-13.7 (± 2.65)	-21.6 (± 2.68)		

Statistical analyses

Statistical analysis title	Primary Endpoint
Comparison groups	Active v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANCOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
All treatment-emergent AEs (serious and non-serious) were captured.	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	18.0
Reporting groups	
Reporting group title	Active
Reporting group description:	
Vicks Vapour Rub	
Reporting group title	Comparator
Reporting group description:	
Petrolatum	

Serious adverse events	Active	Comparator	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Active	Comparator	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 50 (6.00%)	5 / 50 (10.00%)	
Nervous system disorders			
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 50 (4.00%)	2 / 50 (4.00%)	
occurrences (all)	2	2	
Paraesthesia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
General disorders and administration			

site conditions			
Application site warmth			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Infections and infestations			
Ear infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 January 2015	The amendment allowed a subject who failed eligibility at Day 0 to be re-screened if 1) the subject experienced a new common cold and 2) the reason the subject did not initially qualify was due to a transient, resolved ineligibility (eg, changes in the intensity or duration of the cold or severity of acute sleep issues or prohibited medication changes, etc.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported