Clinical trial results:
A 2-arm, randomised, single - (Investigator) blind, controlled, parallel design study in common cold sufferers experiencing nasal congestion to assess the speed of action of Vicks® VapoRub® (VVR)

Summary

EudraCT number	2013-005006-66
Trial protocol	GB
Global end of trial date	11 March 2014

Results information

Result version number	v1 (current)
This version publication date	09 June 2022
First version publication date	09 June 2022
Summary attachment (see zip file)	Final Report (EudraCT - 2013-005006-66.pdf)

Trial information

Trial identification

Sponsor protocol code	2013118

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	The Procter & Gamble Company
Sponsor organisation address	Mason Business Center, 8700 Mason-Montgomery Road, , Mason, United States, 45040-9462
Public contact	Sue Aspley, Procter&Gamble Tech Centres, aspley.s@pg.com
Scientific contact	Sue Aspley, Procter&Gamble Tech Centres, aspley.s@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	17 June 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 March 2014
Global end of trial reached?	Yes
Global end of trial date	11 March 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the study is to investigate the speed of action of Vicks Vaporub (VVR) and to provide data to design a pivotal study.

Protection of trial subjects:

Common cold patients were exposed to a single dose which minimized risk for any potential adverse events.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 January 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: 50
Worldwide total number of subjects	50
EEA total number of subjects	0

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)	50
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All subjects completed the study with no drop outs.

Pre-assignment period milestones

Number of subjects started	50
Number of subjects completed	50

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:

This was a single - (investigator) blind study, with limited access to the randomization code. 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.

Arms

Are arms mutually exclusive?	Yes
Arm title	Petrolatum

Arm description: -

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

Dosage and administration details:

7.5g Topical application

Arm title	Vicks Vaporub

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Vicks Vaporub
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

7.5g Topical application

Notes:

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

Justification: This was a single - (investigator) blind study, with limited access to the randomization code. 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.

Number of subjects in period 1	Petrolatum	Vicks Vaporub
Started	25	25
Completed	25	25

Baseline characteristics

End points

End points reporting groups	
Reporting group title	Petrolatum
Reporting group description: -	
Reporting group title	Vicks Vaporub
Reporting group description: -	

Primary: Primary	
End point title	Primary
End point description: Primary endpoint: time to first experiencing sensation of nasal cooling.	
End point type	Primary
End point timeframe: Seconds	

End point values	Petrolatum	Vicks Vaporub		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: First Sensation of nasal cooling				
number (not applicable)	25	25		

Statistical analyses

Statistical analysis title	Kaplan-Meier LogRank Analysis
Comparison groups	Petrolatum v Vicks Vaporub
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.05
Method	Median

Secondary: Secondary	
End point title	Secondary
End point description: Secondary endpoint: time to first experiencing sensation of nasal decongestion.	
End point type	Secondary
End point timeframe: Seconds	

End point values	Petrolatum	Vicks Vaporub		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: sensation of nasal decongestion				
number (not applicable)	25	25		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

This was a single day study. Subjects could report adverse events directly after treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17

Reporting groups

Reporting group title	Petrolatum
Reporting group description: -	
Reporting group title	Vicks Vaporub
Reporting group description: -	

Serious adverse events	Petrolatum	Vicks Vaporub	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (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	Petrolatum	Vicks Vaporub	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No Adverse Events were reported during this single day trial.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported