Clinical trial results:
A monocenter, double-blind, randomized study to assess the kinetic of antiperspirant efficacy of Glycopyrrolate 0.2% and 0.02% versus placebo during 4 days of topical applications on axilla of healthy volunteers.

Summary

EudraCT number	2014-001796-31
Trial protocol	DE
Global end of trial date	16 February 2015

Results information

Result version number	v1 (current)
This version publication date	23 July 2021
First version publication date	23 July 2021
Summary attachment (see zip file)	Summary study report GLYCAD (ACR-GLYCAD 1375_Summary Study Report_FINAL_V1.0.pdf)

Trial information

Trial identification

Sponsor protocol code	ACR/GLYCAD/1375

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	L'OREAL RESEARCH & INNOVATION
Sponsor organisation address	1 Avenue Eugène Schueller, Aulnay-sous-Bois , France, 93600
Public contact	NOUVEAU Stéphanie Head of Clinical Platform, L'OREAL RESEARCH & INNOVATION, +33 (0)148 68 91 84, stephanie.nouveau@rd.loreal.com
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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	02 February 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 February 2015
Global end of trial reached?	Yes
Global end of trial date	16 February 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study is to assess the kinetic of antiperspirant efficacy of Glycopyrrolate 0.2% and 0.02% versus placebo on the axillae of healthy volunteers, during 4 days of topical applications.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 December 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	Germany: 66
Worldwide total number of subjects	66
EEA total number of subjects	66

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)	66
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

First subject screened: 15 December 2014 ; First subject randomized: 06 January 2015 : in Germany

Pre-assignment

Screening details:

Wash out period before the screening (D1 to D21): the subject was asked to wash his axillae twice a day with the unscented soap and to use only the deodorant (without antiperspirant ingredients) provided for the study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Data analyst, Assessor, Subject

Blinding implementation details:

The study was conducted double-blind with individual patient kits for the respective randomization numbers.
The analysis was performed in accordance with the statistical analysis methodology established prior to the study unblinding. The authorization to unblind the study was given by L'OREAL RESEARCH after database validation.

Arms

Are arms mutually exclusive?	Yes
Arm title	Glycopyrrolate 0.2% compared to Glycopyrrolate 0.02%

Arm description:

Each subject received Glycopyrrolate 0.2% and Glycopyrrolate 0.02% in a randomized manner during 4 consecutive days on axillae

Arm type	Experimental
Investigational medicinal product name	Glycopyrrolate
Investigational medicinal product code	
Other name	(3RS)-3-[(2SR)-(2-cyclopentyl-2-hydroxy-2-phenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

0.4 g (400µl) once a day for 4 days by topical application on the investigational areas (axillae) depending on randomization

Arm title	Glycopyrrolate 0.2% compared to placebo

Arm description:

Each subject received Glycopyrrolate 0.2% or placebo in a randomized manner during 4 consecutive days on axillae

Arm type	Experimental
Investigational medicinal product name	Glycopyrrolate
Investigational medicinal product code	t
Other name	(3RS)-3-[(2SR)-(2-cyclopentyl-2-hydroxy-2-phenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

0.4 g (400µl) once a day for 4 days by topical application on the investigational areas (axillae) depending on randomization

Investigational medicinal product name	Vehicle without active
Investigational medicinal product code	
Other name	Natrosol, Ethanol, Water
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

0.4 g (400µl) once a day for 4 days by Topical application on the investigational areas (axillae) depending on randomization

Arm title	Glycopyrrolate 0.02% compared to placebo

Arm description:

Each subject received Glycopyrrolate 0.02% or placebo (vehicle) in a randomized manner during 4 consecutive days on axillae

Arm type	Experimental
Investigational medicinal product name	Glycopyrrolate
Investigational medicinal product code	
Other name	(3RS)-3-[(2SR)-(2-cyclopentyl-2-hydroxy-2-phenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

0.4 g (400µl) once a day for 4 days by topical application on the investigational areas (axillae) depending on randomization

Investigational medicinal product name	Vehicle without active
Investigational medicinal product code	
Other name	Natrosol, Ethanol, Water
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

0.4 g (400µl) once a day for 4 days by Topical application on the investigational areas (axillae) depending on randomization

Number of subjects in period 1	Glycopyrrolate 0.2% compared to Glycopyrrolate 0.02%	Glycopyrrolate 0.2% compared to placebo	Glycopyrrolate 0.02% compared to placebo
Started	22	22	22
Completed	22	21	17
Not completed	0	1	5
Consent withdrawn by subject	-	-	1
Protocol deviation	-	1	4

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	66	66	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	66	66	
From 65-84 years	0	0	
85 years and over	0	0	
SUBJECT AGE	0	0	
Age continuous			
The mean age of the 66 adults was 32.7 years (range 18 to 45 years).			
Units: years			
arithmetic mean	32.7		
full range (min-max)	18 to 45	-	
Gender categorical			
there were 31 (47%) women and 35 (53%) men			
Units: Subjects			
Female	31	31	
Male	35	35	
Fitzpatrick phototype Units: Subjects			
Fitzpatrick phototype II	7	7	
Fitzpatrick phototype III	59	59	

End points

End points reporting groups

Reporting group title	Glycopyrrolate 0.2% compared to Glycopyrrolate 0.02%
Reporting group description:	
Each subject received Glycopyrrolate 0.2% and Glycopyrrolate 0.02% in a randomized manner during 4 consecutive days on axillae	
Reporting group title	Glycopyrrolate 0.2% compared to placebo
Reporting group description:	
Each subject received Glycopyrrolate 0.2% or placebo in a randomized manner during 4 consecutive days on axillae	
Reporting group title	Glycopyrrolate 0.02% compared to placebo
Reporting group description:	
Each subject received Glycopyrrolate 0.02% or placebo (vehicle) in a randomized manner during 4 consecutive days on axillae	

Primary: log reduction of sweat change from baseline (D22)

End point title	log reduction of sweat change from baseline (D22)
End point description:	
End point type	Primary
End point timeframe:	
The amount of sweat was measured gravimetrically at baseline (D22) before the first application of investigational products, at D23; D24, D25 and on D26 , D27 and D28 after application of products.	

End point values	Glycopyrrolate 0.2% compared to Glycopyrrolate 0.02%	Glycopyrrolate 0.2% compared to placebo	Glycopyrrolate 0.02% compared to placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	21	17	
Units: mg				
number (not applicable)	22	21	17	

Statistical analyses

Statistical analysis title	ANCOVA
Comparison groups	Glycopyrrolate 0.2% compared to placebo v Glycopyrrolate 0.02% compared to placebo v Glycopyrrolate 0.2% compared to Glycopyrrolate 0.02%

Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.001 [2]
Method	ANCOVA

Notes:

[1] - two - sided test

[2] - P-value < 0.001 for 0.2 % Glycopyrolate vs placebo at D26
P-value = 0.178 for 0.02 % Glycopyrolate vs placebo at D26

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The obligation to report Adverse Event starts with the enrolment of the subject into the study and continues throughout the whole study.

Assessment type	Systematic

Dictionary used

Dictionary name	not applicable
Dictionary version	NA

Reporting groups

Reporting group title	Glycopyrrolate 0.2% compared to Glycopyrrolate 0.02%

Reporting group description:

Each subject received 2 different compounds Glycopyrrolate 0.2% compared to Glycopyrrolate 0.02%, according to the randomization on the investigational site on the left and right axilla during 4 consecutive days .

Serious adverse events	Glycopyrrolate 0.2% compared to Glycopyrrolate 0.02%		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Glycopyrrolate 0.2% compared to Glycopyrrolate 0.02%		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 22 (9.09%)		
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	1		

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