



Clinical trial results:

AN OPEN-LABEL STUDY ASSESSING LONG-TERM SAFETY OF DRM04 IN SUBJECTS WITH PRIMARY AXILLARY HYPERHIDROSIS

Summary

EudraCT number	2015-002163-42
Trial protocol	DE
Global end of trial date	12 January 2017

Results information

Result version number	v1 (current)
This version publication date	29 January 2018
First version publication date	29 January 2018

Trial information

Trial identification

Sponsor protocol code	DRM04-HH06
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02553798
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Dermira, Inc.
Sponsor organisation address	275 Middlefield Road, Ste 150, Menlo Park, United States, 94025
Public contact	Chief Medical Officer, Dermira, Inc., 001 6504217202, eugene.bauer@dermira.com
Scientific contact	Chief Medical Officer, Dermira, Inc., 001 6504217202, eugene.bauer@dermira.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	12 January 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 January 2017
Global end of trial reached?	Yes
Global end of trial date	12 January 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to assess the long-term safety of DRM04 Topical Wipes, 3.75% in subjects with primary axillary hyperhidrosis in a minimum of 100 subjects for at least 12 months.

Protection of trial subjects:

This study was conducted in accordance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 August 2015
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: 44
Country: Number of subjects enrolled	United States: 520
Worldwide total number of subjects	564
EEA total number of subjects	44

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)	1
Adolescents (12-17 years)	46
Adults (18-64 years)	512
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subject participated in DRM04-HH04 or DRM04-HH05 study

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	DRM04, 3.75%
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	DRM04, 3.75%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

DRM04 3.75% solution applied once daily to the axillae for up to 44 weeks

Number of subjects in period 1	DRM04, 3.75%
Started	564
Completed	226
Not completed	338
Consent withdrawn by subject	82
Physician decision	1
Study terminated by Sponsor	106
Adverse event, non-fatal	44
Pregnancy	3
Lost to follow-up	92
Protocol deviation	2
Noncompliance	8

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	564	564	
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)	1	1	
Adolescents (12-17 years)	46	46	
Adults (18-64 years)	512	512	
From 65-84 years	5	5	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	309	309	
Male	255	255	

End points

End points reporting groups

Reporting group title	DRM04, 3.75%
Reporting group description: -	

Primary: Long term Safety

End point title	Long term Safety ^[1]
End point description:	

End point type	Primary
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End point timeframe:

Baseline - Week 44/ET

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Uncontrolled trial - no inferential statistics were planned for this study.

End point values	DRM04, 3.75%			
Subject group type	Reporting group			
Number of subjects analysed	550			
Units: Adverse Events and LSRs				
Mild AEs	148			
Moderate AEs	153			
Severe AEs	28			
Mild LSRs	120			
Moderate LSRs	44			
Severe LSRs	15			

Statistical analyses

No statistical analyses for this end point

Secondary: Gravimetrically-Measured Sweat Production

End point title	Gravimetrically-Measured Sweat Production
End point description:	

End point type	Secondary
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End point timeframe:

Baseline - Week 44/ET

End point values	DRM04, 3.75%			
Subject group type	Reporting group			
Number of subjects analysed	430			
Units: mg/5 min				
arithmetic mean (standard deviation)	-95.68 (± 140.806)			

Statistical analyses

No statistical analyses for this end point

Secondary: Hyperhidrosis Disease Severity Score

End point title	Hyperhidrosis Disease Severity Score
End point description:	
End point type	Secondary
End point timeframe:	
Baseline - Week 44/ET	

End point values	DRM04, 3.75%			
Subject group type	Reporting group			
Number of subjects analysed	437			
Units: Changes from Baseline at Week 44/ET				
3 - point improvement	72			
2 - point improvement	204			
1 - point improvement	135			
no improvement	26			

Statistical analyses

No statistical analyses for this end point

Secondary: Quality of Life - DLQI

End point title	Quality of Life - DLQI
End point description:	
End point type	Secondary
End point timeframe:	
Baseline - Week 44/ET	

End point values	DRM04, 3.75%			
Subject group type	Reporting group			
Number of subjects analysed	406			
Units: change from Baseline at Week 44/ET				
arithmetic mean (standard deviation)	-8.7 (\pm 6.24)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline to end of study

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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Reporting groups

Reporting group title	DRM04, 3.75%
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Reporting group description: -

Serious adverse events	DRM04, 3.75%		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 550 (1.27%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 550 (0.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 550 (0.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Mydriasis			
subjects affected / exposed	1 / 550 (0.18%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Suicide attempt			

subjects affected / exposed	1 / 550 (0.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Affective disorder			
subjects affected / exposed	1 / 550 (0.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Diverticulitis			
subjects affected / exposed	1 / 550 (0.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infectious colitis			
subjects affected / exposed	1 / 550 (0.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	DRM04, 3.75%		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	226 / 550 (41.09%)		
General disorders and administration site conditions			
Application site pain			
subjects affected / exposed	35 / 550 (6.36%)		
occurrences (all)	58		
Eye disorders			
Vision blurred			
subjects affected / exposed	37 / 550 (6.73%)		
occurrences (all)	45		
Mydriasis			
subjects affected / exposed	29 / 550 (5.27%)		
occurrences (all)	38		
Gastrointestinal disorders			

Dry mouth subjects affected / exposed occurrences (all)	93 / 550 (16.91%) 136		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	32 / 550 (5.82%) 36		

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