

**Clinical trial results:****A PHASE 3, RANDOMIZED, DOUBLE-BLIND, VEHICLE-CONTROLLED EFFICACY AND SAFETY STUDY OF DRM04 IN SUBJECTS WITH AXILLARY HYPERHIDROSIS****Summary**

EudraCT number	2015-002052-27
Trial protocol	DE
Global end of trial date	31 March 2016

Results information

Result version number	v1 (current)
This version publication date	24 April 2017
First version publication date	24 April 2017

Trial information**Trial identification**

Sponsor protocol code	DRM04-HH04
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02530281
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	Eugene A. Bauer, M.D. Chief Medical Officer, Dermira, Inc., 001 650421-7202, eugene.bauer@dermira.com
Scientific contact	Eugene A. Bauer, M.D. Chief Medical Officer, Dermira, Inc., 001 650421-7202, 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	31 March 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2016
Global end of trial reached?	Yes
Global end of trial date	31 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study will be to assess the efficacy and safety of DRM04 Topical Wipes, 3.75% compared to vehicle when applied once daily for 28 days in subjects with primary axillary hyperhidrosis.

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	31 July 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	United States: 291
Country: Number of subjects enrolled	Germany: 53
Worldwide total number of subjects	344
EEA total number of subjects	53

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)	2
Adolescents (12-17 years)	21
Adults (18-64 years)	316
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening: maximum duration of 35 days

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	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
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 28 days

Arm title	Vehicle
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Vehicle
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

Vehicle solution applied once daily to the axillae for 28 days

Number of subjects in period 1	DRM04, 3.75%	Vehicle
Started	229	115
Completed	208	112
Not completed	21	3
Consent withdrawn by subject	6	1
Adverse event, non-fatal	8	1
scheduled elective surgery	1	-

Lost to follow-up	5	1
non-compliance	1	-

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: DRM04, 3.75%	

Reporting group values	Overall trial	Total	
Number of subjects	344	344	
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)	2	2	
Adolescents (12-17 years)	21	21	
Adults (18-64 years)	316	316	
From 65-84 years	5	5	
85 years and over	0	0	
Gender categorical			
Overall Trial			
Units: Subjects			
Female	190	190	
Male	154	154	

End points

End points reporting groups

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

Primary: Proportion of Subjects with a Minimum 4-Point Improvement in Weekly Mean Score of ASDD Item #2, from Baseline at Week 4

End point title	Proportion of Subjects with a Minimum 4-Point Improvement in Weekly Mean Score of ASDD Item #2, from Baseline at Week 4
End point description:	
End point type	Primary
End point timeframe:	
Baseline - Week 4	

End point values	DRM04, 3.75%	Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	115		
Units: percent	53	28		

Statistical analyses

Statistical analysis title	Co-primary
Comparison groups	DRM04, 3.75% v Vehicle
Number of subjects included in analysis	344
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Primary: Absolute Change in Gravimetrically-Measured Sweat Production at Week 4

End point title	Absolute Change in Gravimetrically-Measured Sweat Production at Week 4
End point description:	
End point type	Primary
End point timeframe:	
Baseline - Week 4	

End point values	DRM04, 3.75%	Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	115		
Units: mg/5 min				
arithmetic mean (standard deviation)	-104.9 (± 284.865)	-91.9 (± 128.018)		

Statistical analyses

Statistical analysis title	Co-primary
Comparison groups	Vehicle v DRM04, 3.75%
Number of subjects included in analysis	344
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.065
Method	ANCOVA

Primary: Absolute Change in Gravimetrically-Measured Sweat Production at Week 4, Excluding Analysis Center 14 (Investigational Sites 412 and 419)

End point title	Absolute Change in Gravimetrically-Measured Sweat Production at Week 4, Excluding Analysis Center 14 (Investigational Sites 412 and 419)
End point description:	
End point type	Primary
End point timeframe:	
Baseline - Week 4	

End point values	DRM04, 3.75%	Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	220	110		
Units: mg/5 min				
arithmetic mean (standard deviation)	-96.2 (± 125.458)	-90.6 (± 129.223)		

Statistical analyses

Statistical analysis title	Sensitivity analysis
Comparison groups	DRM04, 3.75% v Vehicle
Number of subjects included in analysis	330
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.001
Method	ANCOVA

Secondary: Proportion of Subjects with a Minimum 2-grade Improvement in HDSS from Baseline at Week 4

End point title	Proportion of Subjects with a Minimum 2-grade Improvement in HDSS from Baseline at Week 4
End point description:	
End point type	Secondary
End point timeframe:	
Baseline - Week 4	

End point values	DRM04, 3.75%	Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	115		
Units: percent	57	24		

Statistical analyses

Statistical analysis title	Secondary
Comparison groups	Vehicle v DRM04, 3.75%
Number of subjects included in analysis	344
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Proportion of Subjects who have at least a 50% reduction in Gravimetrically-Measured Sweat Production from Baseline at Week 4

End point title	Proportion of Subjects who have at least a 50% reduction in Gravimetrically-Measured Sweat Production from Baseline at Week 4
End point description:	
End point type	Secondary

End point timeframe:

Baseline - Week 4

End point values	DRM04, 3.75%	Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	115		
Units: percent	77	54		

Statistical analyses

Statistical analysis title	Secondary
Comparison groups	DRM04, 3.75% v Vehicle
Number of subjects included in analysis	344
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline - 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: -

Reporting group title	Vehicle
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Reporting group description: -

Serious adverse events	DRM04, 3.75%	Vehicle	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 227 (0.44%)	0 / 114 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Eye disorders			
unilateral mydriasis			
subjects affected / exposed	1 / 227 (0.44%)	0 / 114 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	DRM04, 3.75%	Vehicle	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	68 / 227 (29.96%)	16 / 114 (14.04%)	
General disorders and administration site conditions			
Application site pain			
subjects affected / exposed	20 / 227 (8.81%)	11 / 114 (9.65%)	
occurrences (all)	25	11	
Application site pruritus			
subjects affected / exposed	4 / 227 (1.76%)	6 / 114 (5.26%)	
occurrences (all)	6	7	

Eye disorders			
Mydriasis			
subjects affected / exposed	15 / 227 (6.61%)	0 / 114 (0.00%)	
occurrences (all)	16	0	
Gastrointestinal disorders			
dry mouth			
subjects affected / exposed	43 / 227 (18.94%)	4 / 114 (3.51%)	
occurrences (all)	56	4	

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