Clinical trial results:
A multi-center, randomized, observer-blind trial to compare the irritant potential of the two topical acne formulations Acanya® Gel and Epiduo® Gel on acneic skin in a split-face assessment during a 14-day treatment period

Summary

EudraCT number	2010-020796-24
Trial protocol	DE
Global end of trial date	29 August 2011

Results information

Result version number	v1 (current)
This version publication date	04 January 2020
First version publication date	04 January 2020

Trial information

Trial identification

Sponsor protocol code	DPSI-Acanya-P4-03 / 300108BS

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Dow Pharmaceutical Sciences, Inc.
Sponsor organisation address	1330 Redwood Way, Petaluma, United States, 94954-7121
Public contact	Project manager, Dow Pharmaceuticals, +1 707-796-7226,
Scientific contact	Project manager, Dow Pharmaceuticals, +1 707-796-7226,

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	29 August 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 August 2011
Global end of trial reached?	Yes
Global end of trial date	29 August 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective is to assess the irritant potential of Acanya® Gel compared to Epiduo® Gel on acneic skin

Protection of trial subjects:

The clinical trial was performed in accordance with the currently valid declaration of Helsinki as well as German regulations. The ICH guideline for GCP (January 1997) was observed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 November 2010
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: 21
Worldwide total number of subjects	21
EEA total number of subjects	21

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)	21
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Male or female subjects aged 18 years or older were eligible for this clinical trial insofar that they suffered from acne vulgaris in the face.

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	No
Arm title	Acanya® Gel

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Acanya® Gel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Applied once daily during the visits by a study nurse over a treatment period of 14 days, to one half of the face.

Arm title	Epiduo® Gel

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Epiduo® Gel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Applied once daily during the visits by a study nurse over a treatment period of 14 days, to one half of the face.

Arm title	Not corresponding to a specific test field

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Acanya® Gel	Epiduo® Gel	Not corresponding to a specific test field
Started	21	21	21
Completed	19	19	19
Not completed	2	2	2
Consent withdrawn by subject	2	2	2

Baseline characteristics

Reporting groups

Reporting group title	Treatment

Reporting group description: -

Reporting group values	Treatment	Total	
Number of subjects	21	21	
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	21.3		
standard deviation	± 3.3	-	
Gender categorical Units: Subjects			
Female	10	10	
Male	11	11	
Dryness - Clinical Assessment Units: Score			
arithmetic mean	0.1		
standard deviation	± 0.30	-	
Erythema - Clinical Assessment Units: Score			
arithmetic mean	0.1		
standard deviation	± 0.36	-	

End points

End points reporting groups

Reporting group title	Acanya® Gel
Reporting group description: -	
Reporting group title	Epiduo® Gel
Reporting group description: -	
Reporting group title	Not corresponding to a specific test field
Reporting group description: -	

Primary: Dryness - Change in Clinical Assessment at Week 2

End point title	Dryness - Change in Clinical Assessment at Week 2[1]
End point description:	
End point type	Primary
End point timeframe:	
2 weeks	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: One of two treatments was randomly assigned to one side of the face. The other side of the face received the other treatment. The two treated areas were compared to each other. There were 21 subjects in the study.

End point values	Acanya® Gel	Epiduo® Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	21		
Units: Score				
arithmetic mean (standard deviation)	0.4 (± 0.75)	1.0 (± 0.97)		

Statistical analyses

Statistical analysis title	Comparison of treatment groups
Comparison groups	Acanya® Gel v Epiduo® Gel
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.0054
Method	Wilcoxon (Mann-Whitney)

Notes:

[2] - Note that only 21 subjects are in the analysis. One side of the face was treated with one treatment group and the other side of the face was treated with the other treatment group.

Primary: Erythema - Change in Clinical Assessment at Week 2

End point title	Erythema - Change in Clinical Assessment at Week 2[3]
End point description:	

End point type	Primary

End point timeframe:

2 weeks

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: One of two treatments was randomly assigned to one side of the face. The other side of the face received the other treatment. The two treated areas were compared to each other. There were 21 subjects in the study.

End point values	Acanya® Gel	Epiduo® Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21[4]	21[5]		
Units: Score				
arithmetic mean (standard deviation)	0.7 (± 0.78)	1.3 (± 1.01)		

Notes:

[4] - 21 subjects received this treatment on one half of the face.

[5] - 21 subjects received this treatment on one half of the face.

Statistical analyses

Statistical analysis title	Comparison of treatment groups
Comparison groups	Acanya® Gel v Epiduo® Gel
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0.002
Method	Wilcoxon (Mann-Whitney)

Notes:

[6] - Note that only 21 subjects are in the analysis. One side of the face was treated with one treatment group and the other side of the face was treated with the other treatment group.

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 14 days	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.0
Reporting groups	
Reporting group title	Acanya® Gel
Reporting group description: -	
Reporting group title	Epiduo® Gel
Reporting group description: -	
Reporting group title	Not corresponding to a specific test field
Reporting group description: -	

Serious adverse events	Acanya® Gel	Epiduo® Gel	Not corresponding to a specific test field
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	Acanya® Gel	Epiduo® Gel	Not corresponding to a specific test field
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	4 / 21 (19.05%)
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Infections and infestations			
Nasopharygitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Oral herpes			

subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 21 (0.00%) 0	1 / 21 (4.76%) 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