



## Clinical trial results:

**A single center, randomized, controlled study to determine the irritant potential of topical acne formulations on intact healthy skin on the back following repeated application during a 21-day treatment period**

### Summary

EudraCT number	2009-014550-14
Trial protocol	DE
Global end of trial date	01 February 2010

### 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-P4-02 / 290622BS
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#### 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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	01 February 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 February 2010
Global end of trial reached?	Yes
Global end of trial date	01 February 2010
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

Main objective of the trial:

The primary objective is to assess the irritant potential of Acanya® compared to Duac® and BenzaClin®.

Protection of trial subjects:

The study 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	27 October 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Germany: 33
Worldwide total number of subjects	33
EEA total number of subjects	33

Notes:

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**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)	33
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Men and women aged 18 years or older with healthy skin in the area of the test fields.

### 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
<b>Arm title</b>	Acanya® Gel

Arm description: -

Arm type	Experimental
Investigational medicinal product name	clindamycin 1 % / benzoyl peroxide 2.5 %
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Topical application of approximately 200 µl formulation per test field (approximately 2.5 cm<sup>2</sup>) once daily

<b>Arm title</b>	Duac® Topical Gel
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	clindamycin 1 % / benzoyl peroxide 5 %
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Topical application of approximately 200 µl formulation per test field (approximately 2.5 cm<sup>2</sup>) once daily

<b>Arm title</b>	BenzaClin® Topical Gel
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	clindamycin 1 % / benzoyl peroxide 5 %
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Topical application of approximately 200 µl formulation per test field (approximately 2.5 cm<sup>2</sup>) once daily

<b>Arm title</b>	Acanya® Gel + topical retinoid
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Arm description: -

Arm type	Active comparator
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Investigational medicinal product name	clindamycin 1 % / benzoyl peroxide 2.5 %
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use
Dosage and administration details:	
Topical application of approximately 200 µl formulation per test field (approximately 2.5 cm2) once daily	
<b>Arm title</b>	Petrolatum
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Petrolatum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use
Dosage and administration details:	
Topical application of approximately 200 µl formulation per test field (approximately 2.5 cm2) once daily	
<b>Arm title</b>	Sodium lauryl sulfate
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	0.25 % sodium lauryl sulfate in water
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use
Dosage and administration details:	
Topical application of approximately 200 µl formulation per test field (approximately 2.5 cm2) once daily	

<b>Number of subjects in period 1</b>	Acanya® Gel	Duac® Topical Gel	BenzaClin® Topical Gel
Started	33	33	33
Completed	32	32	32
Not completed	1	1	1
Protocol deviation	1	1	1

<b>Number of subjects in period 1</b>	Acanya® Gel + topical retinoid	Petrolatum	Sodium lauryl sulfate
Started	33	33	33
Completed	32	32	32
Not completed	1	1	1
Protocol deviation	1	1	1

## Baseline characteristics

### Reporting groups

Reporting group title	Treatment
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Reporting group description:

There were 33 subjects in the study. Each subject was treated with each treatment group in designated areas on the skin.

Reporting group values	Treatment	Total	
Number of subjects	33	33	
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	43.3		
standard deviation	± 9.8	-	
Gender categorical			
Units: Subjects			
Female	13	13	
Male	20	20	

## End points

### End points reporting groups

Reporting group title	Acanya® Gel
Reporting group description: -	
Reporting group title	Duac® Topical Gel
Reporting group description: -	
Reporting group title	BenzaClin® Topical Gel
Reporting group description: -	
Reporting group title	Acanya® Gel + topical retinoid
Reporting group description: -	
Reporting group title	Petrolatum
Reporting group description: -	
Reporting group title	Sodium lauryl sulfate
Reporting group description: -	

### Primary: Cumulative Irritation Score at Day 22

End point title	Cumulative Irritation Score at Day 22 <sup>[1]</sup>
End point description:	
End point type	Primary
End point timeframe:	
22 days	

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: No confirmatory hypotheses were formulated for this study.

End point values	Acanya® Gel	Duac® Topical Gel	BenzaClin® Topical Gel	Acanya® Gel + topical retinoid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	33	33	33
Units: Score				
arithmetic mean (standard deviation)	34.97 (± 7.35)	32.42 (± 7.55)	35.97 (± 7.70)	42.26 (± 4.29)

End point values	Petrolatum	Sodium lauryl sulfate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	33		
Units: Score				
arithmetic mean (standard deviation)	0.82 (± 1.51)	50.67 (± 1.11)		

### Statistical analyses



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

22 days

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	13
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### Reporting groups

Reporting group title	Not corresponding to a treatment
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Reporting group description: -

Reporting group title	SLS treated area
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Reporting group description:

Each subject had designed areas treated with each treatment group.

<b>Serious adverse events</b>	Not corresponding to a treatment	SLS treated area	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (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 %

<b>Non-serious adverse events</b>	Not corresponding to a treatment	SLS treated area	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 33 (6.06%)	1 / 33 (3.03%)	
General disorders and administration site conditions			
Application site pruritis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 33 (3.03%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 33 (3.03%)	0 / 33 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			



Bronchitis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 33 (0.00%)	
occurrences (all)	1	0	

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported