Clinical trial results:
A Multicentre, Randomized, Assessor-blind, Comparator-Controlled, Parallel-Group Clinical Trial to Establish the Efficacy and Safety of Duac™(1% clindamycin as clindamycin phosphate and 5% benzoyl peroxide) Once Daily Gel Compared with Clindamycin Phosphate gel (1% clindamycin as clindamycin phosphate) twice daily in the Treatment of Mild to Moderate Acne Vulgaris.

Summary

EudraCT number	2015-004909-16
Trial protocol	Outside EU/EEA
Global end of trial date	20 April 2014

Results information

Result version number	v1 (current)
This version publication date	29 December 2016
First version publication date	29 December 2016

Trial information

Trial identification

Sponsor protocol code	114543

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 June 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

TBD

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 April 2013
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	China: 1016
Worldwide total number of subjects	1016
EEA total number of subjects	0

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)	56
Adults (18-64 years)	960
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 1020 participants were randomized and enrolled in this study. Four participants were excluded following randomization because they did not receive at least one application of the study product. Overall, 1016 participants were included in the ITT population and 903 participants were included in the PP population.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Assessor[1]

Blinding implementation details:

The protocol was conducted using an assessor-blinded design. This was an assessor-blinded study; therefore, assessors who assessed the lesion count, ISGA and local tolerability, and programmers and the statisticians were blinded, while the other individuals involved in the conduct of clinical study were not blinded to investigational product allocations. The assessor was unaware of which investigational product was being used.

Arms

Are arms mutually exclusive?	Yes
Arm title	Duac Once Daily Gel

Arm description:

Participants (Par.) topically applied Duac Once Daily Gel (combination of clindamycin phosphate [equivalent to 1% clindamycin] and 5% benzoyl peroxide) in the evening to facial acne for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Duac gel (1% clindamycin as clindamycin phosphate and 5% benzoyl peroxide)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Duac gel (once daily in the evening) for 12 weeks

Arm title	Dalin Gel

Arm description:

Participants topically applied Dalin Gel (clindamycin phosphate [equivalent to 1% clindamycin]) twice daily (once in the morning and once in the evening) to facial acne for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Dalin gel (1% clindamycin as clindamycin phosphate)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Dalin gel twice daily in the morning and evening by the participants for 12 weeks

Notes:
[1] - The roles blinded appear inconsistent with a simple blinded trial.
Justification: This study was conducted using an assessor-blinded design.

Number of subjects in period 1	Duac Once Daily Gel	Dalin Gel
Started	500	516
Completed	430	445
Not completed	70	71
Got Well	-	1
Par. not Willing to Continue Treatment	-	1
Job Transfer	-	1
Recovered	1	-
Consent withdrawn by subject	18	18
Drug Release Error	1	-
Failure to Meet Randomization Criteria	1	-
Adverse event, non-fatal	12	4
Par. Unable to Come to the Hospital	-	1
Pregnancy	1	-
Improper Facial Procedure	-	1
Par. Improved, Voluntary (Vol) exit	1	-
Par. Conscious Ineffective Vol Exit	1	-
Poor Perceived Efficacy	1	-
Lost to follow-up	22	26
Par. Refused to Hospital Visits	-	1
Protocol deviation	5	5
Lack of efficacy	6	11
Poor Conscious Effect	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Duac Once Daily Gel
Reporting group description:	
Participants (Par.) topically applied Duac Once Daily Gel (combination of clindamycin phosphate [equivalent to 1% clindamycin] and 5% benzoyl peroxide) in the evening to facial acne for 12 weeks.	
Reporting group title	Dalin Gel
Reporting group description:	
Participants topically applied Dalin Gel (clindamycin phosphate [equivalent to 1% clindamycin]) twice daily (once in the morning and once in the evening) to facial acne for 12 weeks.	

Reporting group values	Duac Once Daily Gel	Dalin Gel	Total
Number of subjects	500	516	1016
Age categorical Units: Subjects			
Age continuous			
Age continuous description			
Units: years			
arithmetic mean	23.4	23.3	
standard deviation	± 4.64	± 4.29	-
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	382	383	765
Male	118	133	251
Race/Ethnicity, Customized Units: Subjects			
Asian	500	515	1015
White	0	1	1

End points

End points reporting groups

Reporting group title	Duac Once Daily Gel
Reporting group description:	
Participants (Par.) topically applied Duac Once Daily Gel (combination of clindamycin phosphate [equivalent to 1% clindamycin] and 5% benzoyl peroxide) in the evening to facial acne for 12 weeks.	
Reporting group title	Dalin Gel
Reporting group description:	
Participants topically applied Dalin Gel (clindamycin phosphate [equivalent to 1% clindamycin]) twice daily (once in the morning and once in the evening) to facial acne for 12 weeks.	

Primary: Absolute change in total lesion count from Baseline to Week 12

End point title	Absolute change in total lesion count from Baseline to Week 12
End point description:	
The assessor performed a count of inflammatory lesions (IL) (papules, pustules, nodules, and cysts), non-inflammatory lesions (NIL) (open and closed comedones) and total lesions (the sum of IL and NIL) at each study visit. Lesion counts were confined to the face. Change from Baseline at Week 12 was calculated as the value at Week 12 minus the value at Baseline. Parameters were estimated using analysis of covariance (ANCOVA) with treatment, center, treatment-by-centre interaction and Baseline lesion count in the model. Missing values were imputed using the last observation carried forward (LOCF), i.e., the last available observation was used to estimate subsequent missing data. Intent-to-Treat (ITT) Population: all participants who were randomized and received at least one dose of study medication.	
End point type	Primary
End point timeframe:	
Baseline (Week 0) and Week 12	

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	484[1]	499[2]		
Units: Change in lesion count				
least squares mean (standard error)	-55.7 (± 1.05)	-51.2 (± 1.03)		

Notes:

[1] - ITT Population

[2] - ITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Duac Once Daily Gel v Dalin Gel

Number of subjects included in analysis	983
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	-1.6

Primary: Absolute change in total lesion count from Baseline to Week 12

End point title	Absolute change in total lesion count from Baseline to Week 12

End point description:

The assessor performed a count of inflammatory lesions (IL) (papules, pustules, nodules, and cysts), non-inflammatory lesions (NIL) (open and closed comedones) and total lesions (the sum of IL and NIL) at each study visit. Lesion counts were confined to the face. Change from Baseline at Week 12 was calculated as the value at Week 12 minus the value at Baseline. Parameters were estimated using analysis of covariance (ANCOVA) with treatment, center, treatment-by-centre interaction and Baseline lesion count in the model. Missing values were imputed using the last observation carried forward (LOCF), i.e., the last available observation was used to estimate subsequent missing data.

Per-Protocol (PP) Population: all participants included in the ITT Population who did not have a noteworthy protocol deviation that influenced effect.

End point type	Primary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	433[3]	449[4]		
Units: Change in lesion count				
least squares mean (standard error)	-56.7 (± 0.97)	-52.1 (± 0.96)		

Notes:

[3] - PP Population

[4] - PP Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Dalin Gel v Duac Once Daily Gel

Number of subjects included in analysis	882
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.3
upper limit	-1.9

Primary: Number of participants with an improvement of 2 grades in the Investigator Static Global Assessment (ISGA) score from Baseline to Week 12

End point title	Number of participants with an improvement of 2 grades in the Investigator Static Global Assessment (ISGA) score from Baseline to Week 12

End point description:

ISGA success is defined as the improvement of 2 grades or more in the participant's acne severity scale at Week 12. Acne severity of the participants' face was assessed by the assessor using the ISGA scale, ranging from 0 to 4: 0=clear skin with no ILs or NILs; 1=almost clear: rare NIL with no more than one small IL; 2=mild, some NILs with no more than a few ILs (papules/pustules only, no nodular lesions [NLs]); 3=moderate, up to many NILs and may have some ILs, but no more than one small NL; 4=severe: up to many NILs and ILs, but no more than a few NLs. Missing values were imputed using the LOCF, i.e., the last available observation was used to estimate subsequent missing data.

End point type	Primary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	500[5]	516[6]		
Units: Participants	151	117		

Notes:

[5] - ITT Population

[6] - ITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Dalin Gel v Duac Once Daily Gel

Number of subjects included in analysis	1016
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.018
Method	Cochran-Mantel-Haenszel

Primary: Number of participants with an improvement of 2 grades in the Investigator Static Global Assessment (ISGA) score from Baseline to Week 12

End point title	Number of participants with an improvement of 2 grades in the Investigator Static Global Assessment (ISGA) score from Baseline to Week 12

End point description:

ISGA success is defined as the improvement of 2 grades or more in the participant's acne severity scale at Week 12. Acne severity of the participants' face was assessed by the assessor using the ISGA scale, ranging from 0 to 4: 0=clear skin with no ILs or NILs; 1=almost clear: rare NIL with no more than one small IL; 2=mild, some NILs with no more than a few ILs (papules/pustules only, no nodular lesions [NLs]); 3=moderate, up to many NILs and may have some ILs, but no more than one small NL; 4=severe: up to many NILs and ILs, but no more than a few NLs. Missing values were imputed using the LOCF, i.e., the last available observation was used to estimate subsequent missing data .

End point type	Primary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	442[7]	461[8]		
Units: Participants	142	110		

Notes:

[7] - PP Population

[8] - PP Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Dalin Gel v Duac Once Daily Gel
Number of subjects included in analysis	903
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.013
Method	Cochran-Mantel-Haenszel

Secondary: Absolute change in inflammatory lesion counts and non-inflammatory lesion counts from Baseline to Week 12

End point title	Absolute change in inflammatory lesion counts and non-inflammatory lesion counts from Baseline to Week 12

End point description:

The assessor performed a count of ILs (papules, pustules, nodules, and cysts), NILs (open and closed comedones at each study visit. Lesion counts were confined to the face. Change from Baseline at Week 12 was calculated as the value at Week 12 minus the value at Baseline. Analysis of covariance (ANCOVA) model was used with terms for Baseline lesion count, treatment, and center. Missing values were imputed using the LOCF, i.e., the last available observation was used to estimate subsequent missing data.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	484[9]	499[10]		
Units: Lesions				
least squares mean (standard error)				
IL	-20.6 (± 0.36)	-19.7 (± 0.35)		
NIL	-35 (± 0.83)	-31.6 (± 0.82)		

Notes:

[9] - ITT Population

[10] - ITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 2
Comparison groups	Duac Once Daily Gel v Dalin Gel
Number of subjects included in analysis	983
Analysis specification	Pre-specified
Analysis type	other[11]
P-value	= 0.004
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.7
upper limit	-1.1

Notes:

[11] - Statistical data for the category=NIL

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Statistical data for the category=IL

Comparison groups	Duac Once Daily Gel v Dalin Gel

Number of subjects included in analysis	983
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.077
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	0.1

Secondary: Absolute change in inflammatory lesion counts and non-inflammatory lesion counts from Baseline to Week 12

End point title	Absolute change in inflammatory lesion counts and non-inflammatory lesion counts from Baseline to Week 12

End point description:

The assessor performed a count of ILs (papules, pustules, nodules, and cysts), NILs (open and closed comedones at each study visit. Lesion counts were confined to the face. Change from Baseline at Week 12 was calculated as the value at Week 12 minus the value at Baseline. Analysis of covariance (ANCOVA) model was used with terms for Baseline lesion count, treatment, and center. Missing values were imputed using the LOCF, i.e., the last available observation was used to estimate subsequent missing data.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	433[12]	449[13]		
Units: Lesions				
least squares mean (standard error)				
IL	-20.9 (± 0.34)	-19.9 (± 0.34)		
NIL	-35.7 (± 0.78)	-32.3 (± 0.77)		

Notes:

[12] - PP Population

[13] - PP Population

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Statistical data for the category=IL

Comparison groups	Dalin Gel v Duac Once Daily Gel

Number of subjects included in analysis	882
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.028
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	-0.1

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Statistical data for the category=NIL	
Comparison groups	Dalin Gel v Duac Once Daily Gel
Number of subjects included in analysis	882
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	-1.2

Secondary: Percent change in inflammatory, non-inflammatory and total lesion counts from Baseline to Week 12

End point title	Percent change in inflammatory, non-inflammatory and total lesion counts from Baseline to Week 12

End point description:

The assessor performed a count of ILs (papules, pustules, nodules, and cysts), NILs (open and closed comedones) and total lesions (the sum of ILs and NILs) at each study visit. Lesion counts were confined to the face. Change from Baseline at Week 12 was calculated as the value at Week 12 minus the value at Baseline. Analysis of covariance (ANCOVA) model was used with terms for Baseline lesion count, treatment, and center. Missing values were imputed using the LOCF, i.e., the last available observation was used to estimate subsequent missing data.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	484[14]	499[15]		
Units: Percent change in lesions				
least squares mean (standard error)				
IL	-0.78 (± 0.013)	-0.75 (± 0.013)		
NIL	-0.67 (± 0.018)	-0.6 (± 0.018)		
Total	-0.72 (± 0.013)	-0.67 (± 0.013)		

Notes:

[14] - ITT Population

[15] - ITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Statistical data for the category=IL	
Comparison groups	Duac Once Daily Gel v Dalin Gel
Number of subjects included in analysis	983
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.08
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.06
upper limit	0

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Statistical data for the category=NIL	
Comparison groups	Duac Once Daily Gel v Dalin Gel
Number of subjects included in analysis	983
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.004
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.12
upper limit	-0.02

Statistical analysis title	Statistical analysis 3
Statistical analysis description: Statisticial data for the category=Total	
Comparison groups	Duac Once Daily Gel v Dalin Gel
Number of subjects included in analysis	983
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.003
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	-0.02

Secondary: Percent change in inflammatory, non-inflammatory and total lesion counts from Baseline to Week 12

End point title	Percent change in inflammatory, non-inflammatory and total lesion counts from Baseline to Week 12

End point description:

The assessor performed a count of ILs (papules, pustules, nodules, and cysts), NILs (open and closed comedones) and total lesions (the sum of ILs and NILs) at each study visit. Lesion counts were confined to the face. Change from Baseline at Week 12 was calculated as the value at Week 12 minus the value at Baseline. Analysis of covariance (ANCOVA) model was used with terms for Baseline lesion count, treatment, and center. Missing values were imputed using the LOCF, i.e., the last available observation was used to estimate subsequent missing data.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	433[16]	449[17]		
Units: Percent change in lesions				
least squares mean (standard error)				
IL	-0.8 (± 0.012)	-0.76 (± 0.012)		
NIL	-0.7 (± 0.018)	-0.61 (± 0.017)		
Total	-0.74 (± 0.012)	-0.68 (± 0.012)		

Notes:
[16] - PP Population
[17] - PP Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Statistical data for the category=IL	
Comparison groups	Dalin Gel v Duac Once Daily Gel
Number of subjects included in analysis	882
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.025
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	0

Statistical analysis title	Statistical analysis 3
Statistical analysis description: Statistical data for the category=Total	
Comparison groups	Dalin Gel v Duac Once Daily Gel
Number of subjects included in analysis	882
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	-0.03

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Statistical data for the category=NIL	
Comparison groups	Dalin Gel v Duac Once Daily Gel

Number of subjects included in analysis	882
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	-0.04

Secondary: Number of participants who had an ISGA score of 0 or 1 at Week 12

End point title	Number of participants who had an ISGA score of 0 or 1 at Week 12

End point description:

The assessor evaluated the acne severity of the participants' face using the ISGA scale, ranging from 0 to 4: 0=clear skin with no ILs or NILs; 1=almost clear: rare NIL with no more than one small IL; 2=mild, some NILs with no more than a few ILs (papules/pustules only, no nodular lesions [NLs]); 3=moderate, up to many NILs and may have some ILs, but no more than one small NL; 4=severe: up to many NILs and ILs, but no more than a few NLs. Missing values were imputed using the LOCF, i.e., the last available observation was used to estimate subsequent missing data.

End point type	Secondary

End point timeframe:

Week 12

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	500[18]	516[19]		
Units: Participants	209	151		

Notes:

[18] - ITT Population

[19] - ITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Dalin Gel v Duac Once Daily Gel
Number of subjects included in analysis	1016
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Number of participants who had an ISGA score of 0 or 1 at Week 12

End point title	Number of participants who had an ISGA score of 0 or 1 at Week 12

End point description:

The assessor evaluated the acne severity of the participants' face using the ISGA scale, ranging from 0 to 4: 0=clear skin with no ILs or NILs; 1=almost clear: rare NIL with no more than one small IL; 2=mild, some NILs with no more than a few ILs (papules/pustules only, no nodular lesions [NLs]); 3=moderate, up to many NILs and may have some ILs, but no more than one small NL; 4=severe: up to many NILs and ILs, but no more than a few NLs. Missing values were imputed using the LOCF, i.e., the last available observation was used to estimate subsequent missing data.

End point type	Secondary

End point timeframe:

Week 12

End point values	Duac Once Daily Gel	Dalin Gel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	442[20]	461[21]		
Units: Participants	196	144		

Notes:

[20] - PP Population

[21] - PP Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Duac Once Daily Gel v Dalin Gel
Number of subjects included in analysis	903
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:

Serious adverse events (SAEs) and non-serious AEs were collected from the start of study treatment until the end of study treatment (up to Week 12).

Adverse event reporting additional description:

SAEs and non-serious AEs are reported for the Intent-to-Treat Population, comprised of all participants who were randomized and received at least one dose of study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	Duac Once Daily Gel

Reporting group description:

Participants (Par.) topically applied Duac Once Daily Gel (combination of clindamycin phosphate [equivalent to 1% clindamycin] and 5% benzoyl peroxide) in the evening to facial acne for 12 weeks.

Reporting group title	Dalin Gel

Reporting group description:

Participants topically applied Dalin Gel (clindamycin phosphate [equivalent to 1% clindamycin]) twice daily (once in the morning and once in the evening) to facial acne for 12 weeks.

Serious adverse events	Duac Once Daily Gel	Dalin Gel	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 500 (0.20%)	0 / 516 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Thermal burn	Additional description: SAEs and non-serious AEs are reported for the Intent-to-Treat Population, comprised of all participants who were randomized and received at least one dose of study medication.		
subjects affected / exposed	1 / 500 (0.20%)	0 / 516 (0.00%)	
occurrences causally related to treatment / all	0 / 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	Duac Once Daily Gel	Dalin Gel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 500 (5.20%)	4 / 516 (0.78%)	
General disorders and administration site conditions			

Application site erythema subjects affected / exposed occurrences (all)	26 / 500 (5.20%) 35	4 / 516 (0.78%) 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