Clinical trial results:
Effect of Patient Education on Treatment Adherence and Satisfaction among Acne Patients Receiving Once-Daily EpiduoTM Gel Treatment in Primary Care Clinics

Summary

EudraCT number	2014-002509-39
Trial protocol	GB
Global end of trial date	08 June 2015

Results information

Result version number	v1 (current)
This version publication date	01 January 2017
First version publication date	01 January 2017

Trial information

Trial identification

Sponsor protocol code	RD.03.SPR.102710

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02307266
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Galderma R&D
Sponsor organisation address	2400 route des colles, Biot, France, 06110
Public contact	Clinical Projet Manager, GALDERMA R&D, 33 493957068, gaelle.charier@galderma.com
Scientific contact	Clinical Projet Manager, GALDERMA R&D, 33 493957068, gaelle.charier@galderma.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	01 July 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 June 2015
Global end of trial reached?	Yes
Global end of trial date	08 June 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to evaluate the effect of a supplementary patient education intervention (in addition to the standard-of-care patient eduction) on treatment adherence and satisfaction among acne patients receiving once daily Epiduo Gel treatment in primary carec clinics.

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 November 2014
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 Kingdom: 97
Worldwide total number of subjects	97
EEA total number of subjects	97

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)	39
Adults (18-64 years)	58
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:
No screening

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Standard of care + supplementary education

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Adapalene 0.1% / Benzoyl peroxide 2.5%
Investigational medicinal product code	
Other name	Epiduo
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:
application on the face, once daily

Arm title	Standard of care

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Adapalene 0.1% / Benzoyl peroxide 2.5%
Investigational medicinal product code	
Other name	Epiduo
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:
application on the face, once daily

Arm title	Standard of care + additional visits

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Adapalene 0.1% / Benzoyl peroxide 2.5%
Investigational medicinal product code	
Other name	Epiduo
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:
application on the face, once daily

Number of subjects in period 1	Standard of care + supplementary education	Standard of care	Standard of care + additional visits
Started	33	33	31
Completed	25	32	25
Not completed	8	1	6
Consent withdrawn by subject	2	-	1
Adverse event, non-fatal	3	1	5
Lost to follow-up	3	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Standard of care + supplementary education
Reporting group description: -	
Reporting group title	Standard of care
Reporting group description: -	
Reporting group title	Standard of care + additional visits
Reporting group description: -	

Reporting group values	Standard of care + supplementary education	Standard of care	Standard of care + additional visits
Number of subjects	33	33	31
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	8	14	17
Adults (18-64 years)	25	19	14
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	24.1	21	22.5
standard deviation	± 9.6	± 7.9	± 11.1
Gender categorical Units: Subjects			
Female	22	26	19
Male	11	7	12
Race Units: Subjects			
White	29	26	27
Asian	3	6	4
Other	1	1	0
Skin phototype Units: Subjects			
Phototype I	2	3	2
Phototype II	11	9	11
Phototype III	14	13	12
Phototype IV	5	6	4
Phototype V	1	2	2
Investigator Global Assessment			
Investigator Global Assessment of acne			
Units: Subjects			

1: Almost clear	8	1	3
2: Mild	17	22	20
3: Moderate	8	10	8
Acne history			
Units: years			
arithmetic mean	5.7	4.4	4.7
standard deviation	± 9.3	± 4.6	± 5.6

Reporting group values	Total		
Number of subjects	97		
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)	39		
Adults (18-64 years)	58		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	67		
Male	30		
Race			
Units: Subjects			
White	82		
Asian	13		
Other	2		
Skin phototype			
Units: Subjects			
Phototype I	7		
Phototype II	31		
Phototype III	39		
Phototype IV	15		
Phototype V	5		
Investigator Global Assessment			
Investigator Global Assessment of acne			
Units: Subjects			
1: Almost clear	12		
2: Mild	59		
3: Moderate	26		

Acne history Units: years arithmetic mean standard deviation	- 		

End points

End points reporting groups

Reporting group title	Standard of care + supplementary education
Reporting group description: -	
Reporting group title	Standard of care
Reporting group description: -	
Reporting group title	Standard of care + additional visits
Reporting group description: -	

Primary: Mean rate of adherence, as assessed by Medical Event Monitoring System (MEMS)

End point title	Mean rate of adherence, as assessed by Medical Event Monitoring System (MEMS)

End point description:

To prevent bias, treatment adhrence was assessed without subject's knowledge using a Medication Event Monitoring System(MEMS). The treatment was placed in a container fitted with a MEMS cap which recorded the time/date every time it was opened and/or closed. A day with at least one opening was considered a day the subject was adherent. Mean rate of adhrence in % corresponds to the number of days the subject was adherent divided by the total number of days of the study (84 days) times 100. Analysis was performed on the "worst-case" population: missing data were considered as non-adherence.

End point type	Primary

End point timeframe:

Week 12

End point values	Standard of care + supplementary education	Standard of care	Standard of care + additional visits	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20[1]	28[2]	23[3]	
Units: Percentage of adherence				
arithmetic mean (standard deviation)	63.1 (± 30.2)	56.5 (± 24.8)	48.2 (± 33.9)	

Notes:

[1] - Worst-case population

[2] - Worst-case population

[3] - Worst-case population

Statistical analyses

Statistical analysis title	Comparison SoC + education vs SoC
Comparison groups	Standard of care + supplementary education v Standard of care

Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.3165
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Comparison SoC + education vs SoC + visits
Comparison groups	Standard of care + supplementary education v Standard of care + additional visits
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.0206
Method	Cochran-Mantel-Haenszel

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Week 12	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.0
Reporting groups	
Reporting group title	Standard of care + supplementary education
Reporting group description: -	
Reporting group title	Standard of care
Reporting group description: -	
Reporting group title	Standard of care + additional visits
Reporting group description: -	

Serious adverse events	Standard of care + supplementary education	Standard of care	Standard of care + additional visits
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 31 (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: 2 %

Non-serious adverse events	Standard of care + supplementary education	Standard of care	Standard of care + additional visits
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 33 (21.21%)	6 / 33 (18.18%)	15 / 31 (48.39%)
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 33 (3.03%)	1 / 33 (3.03%)	3 / 31 (9.68%)
occurrences (all)	1	1	3
Dry skin			

subjects affected / exposed	0 / 33 (0.00%)	2 / 33 (6.06%)	2 / 31 (6.45%)
occurrences (all)	0	2	2
Erythema			
subjects affected / exposed	1 / 33 (3.03%)	0 / 33 (0.00%)	2 / 31 (6.45%)
occurrences (all)	1	0	2
Pain of skin			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Rash			
subjects affected / exposed	1 / 33 (3.03%)	1 / 33 (3.03%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Skin burning sensation			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	3
Skin irritation			
subjects affected / exposed	2 / 33 (6.06%)	1 / 33 (3.03%)	0 / 31 (0.00%)
occurrences (all)	2	1	0
Infections and infestations			
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 33 (6.06%)	1 / 33 (3.03%)	1 / 31 (3.23%)
occurrences (all)	2	1	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