Clinical trial results:
Benzaknen® 5% Gel in combination with Dermotivin® Soft Liquid cleanser and non-comedogenic Cetaphil® Dermacontrol Moisturizer SPF30 in the treatment of mild-to-moderate acne vulgaris

Summary

EudraCT number	2015-001448-13
Trial protocol	DE
Global end of trial date	15 January 2016

Results information

Result version number	v2 (current)
This version publication date	10 September 2017
First version publication date	13 May 2017
Version creation reason	• Correction of full data set correction needed on end point value

Trial information

Trial identification

Sponsor protocol code	RD.03.SPR.105041

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02589405
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Galderma R&D
Sponsor organisation address	240 routes des colles, BIOT, France, 06410
Public contact	Stéphanie Leclerc, Galderma R&D, +33 492386706, Stephanie.Leclerc@galderma.com
Scientific contact	Stéphanie Leclerc, Galderma R&D, +33 492386706, Stephanie.Leclerc@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	04 March 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 January 2016
Global end of trial reached?	Yes
Global end of trial date	15 January 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study is to evaluate subject satisfaction with the treatment regimen comprising Benzaknen® 5% Gel in association with Dermotivin® Soft Liquid cleanser and Cetaphil® Dermacontrol Moisturizer SPF30 after 12 weeks of treatment.

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 August 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	Germany: 50
Worldwide total number of subjects	50
EEA total number of subjects	50

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)	21
Adults (18-64 years)	29
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	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Treatment regimen
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Benzaknen® 5% Gel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use
Dosage and administration details: Application on the face once daily	
Investigational medicinal product name	Dermotivin® Soft Liquid soap
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous liquid
Routes of administration	Topical use
Dosage and administration details: Application on the face twice daily (morning/evening)	
Investigational medicinal product name	Cetaphil® Dermacontrol Moisturizer SPF30
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use
Dosage and administration details: Application on the face once daily (evening)	

Number of subjects in period 1	Treatment regimen
Started	50
Completed	46
Not completed	4
Adverse event, non-fatal	3
Subject's request	1

Baseline characteristics

Reporting groups

Reporting group title	Treatment regimen

Reporting group description: -

Reporting group values	Treatment regimen	Total	
Number of subjects	50	50	
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)	0	0	
Adolescents (12-17 years)	21	21	
Adults (18-64 years)	29	29	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	21.8		
standard deviation	± 8	-	
Gender categorical Units: Subjects			
Female	33	33	
Male	17	17	
Skin phototype Units: Subjects			
Phototype I	1	1	
Phototype II	25	25	
Phototype III	21	21	
Phototype IV	3	3	
Investigator Global Assessment Units: Subjects			
Mild	37	37	
Moderate	13	13	
Severe	0	0	
Acne duration Units: Years			
arithmetic mean	9.8		
standard deviation	± 7.4	-	
Total lesions count Units: Lesion			
arithmetic mean	97		
standard deviation	± 45.6	-	
Non-Inflammatory lesions			

Units: Lesions			
arithmetic mean	68.1		
standard deviation	± 37.2	-	
Inflammatory Lesions			
Units: Lesions			
arithmetic mean	28.9		
standard deviation	± 21.7	-	

End points

End points reporting groups

Reporting group title	Treatment regimen
Reporting group description: -	
Subject analysis set title	Treatment regimen
Subject analysis set type	Intention-to-treat

Subject analysis set description:

This population consists of the Intent-to-Treat population, after exclusion of subjects who never took the treatment with certainty based on the monitoring report

Primary: Subject Overall satisfaction with the three-part treatment regimen

End point title	Subject Overall satisfaction with the three-part treatment regimen[1]

End point description:

Percentage of subjects satisfied and very satisfied with the three-part treatment regimen

End point type	Primary

End point timeframe:

Week 12

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 inferential statistics will be performed. All variables have been descriptively summarized on ITT population and on safety population .

End point values	Treatment regimen			
Subject group type	Reporting group			
Number of subjects analysed	48			
Units: Percent subjects				
number (not applicable)	87.5			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Week 12

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18

Reporting groups

Reporting group title	Overall population

Reporting group description: -

Serious adverse events	Overall population		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Overall population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 50 (26.00%)		
Injury, poisoning and procedural complications			

Laceration subjects affected / exposed occurrences (all) Radius fracture subjects affected / exposed occurrences (all)	 1 / 50 (2.00%) 1 1 / 50 (2.00%) 1		
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	 1 / 50 (2.00%) 1		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	 1 / 50 (2.00%) 1		
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Skin exfoliation subjects affected / exposed occurrences (all) Skin irritation subjects affected / exposed occurrences (all)	 1 / 50 (2.00%) 1 1 / 50 (2.00%) 1 1 / 50 (2.00%) 1 3 / 50 (6.00%) 3		
Musculoskeletal and connective tissue disorders Tenosynovitis subjects affected / exposed occurrences (all)	 1 / 50 (2.00%) 1		
Infections and infestations Herpes simplex subjects affected / exposed occurrences (all) Impetigo	 1 / 50 (2.00%) 1 		

subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Mucosal infection			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
Pharyngitis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	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