Clinical trial results:
Double-blind, randomized, vehicle-controlled, multi-centric trial to prove the therapeutic efficacy and tolerability of a liquid acne topical containing Clindamycin phosphate and Sodiumbituminosulfonate, pale versus vehicle and versus each of the single active substances in mild to moderate acne vulgaris

Summary

EudraCT number	2009-013273-17
Trial protocol	DE CZ
Global end of trial date	18 October 2010

Results information

Result version number	v1 (current)
This version publication date	15 December 2018
First version publication date	15 December 2018

Trial information

Trial identification

Sponsor protocol code	KF03/08

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ICHTHYOL-GESELLSCHAFT Cordes, Hermanni & Co. (GmbH & Co.) KG
Sponsor organisation address	Sportallee 85, Hamburg, Germany, 22335
Public contact	Wiebke Fehrs, ICHTHYOL-GESELLSCHAFT Cordes, Hermanni & Co. (GmbH & Co.) KG, +49 4050714-353, wfehrs@ichthyol.de
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000532-PIP01-09
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	18 October 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 October 2010
Global end of trial reached?	Yes
Global end of trial date	18 October 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The proof of superiority of the combination solution as compared to vehicle and to each of the mono preparations with reference to the improvement of acne-appearance in accordance with GAAS (comparison of the score at study start and end) in case of mild to moderate acne vulgaris.

Protection of trial subjects:

All patients were treated with a Acne-Solution, which contains either
- Isopropanol (Vehicle) or
- Isopropanol plus Clindamycin phosphate 1% plus Sodium bituminosulfonate light 6% or
- Isopropanol plus Clindamycin phosphate 1% or
- Isopropanol plus Sodium bituminosulfonate light 6%.

All these solutions were appropriate for the treatment of patients with "mild to moderate acne vulgaris in the area of the face, level 2 – 3 referring to GAAS" for
the limited treatment period of 12 weeks during this study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 February 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	Czech Republic: 84
Country: Number of subjects enrolled	Germany: 68
Worldwide total number of subjects	152
EEA total number of subjects	152

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)	3

Adolescents (12-17 years)	98
Adults (18-64 years)	51
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

date of first enrolment: 12th February 2010
date of last completed: 18th October 2010

Pre-assignment

Screening details:

Patients were included who suffered from mild to moderate acne vulgaris in the face according to classification as per GAAS, level 2 = mild and 3 = moderate.

Period 1

Period 1 title	overall trial (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?	Yes
Arm title	Investigational Medicinal Product (combination arm)

Arm description:

clindamycin 2-dihydrogen phosphate 1.19 %, sodium bituminosulfonate light 6 %; solution

Arm type	Active comparator
Investigational medicinal product name	Akne solution (active comparator) combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

application twice daily

Arm title	Comparator 1 (mono arm)

Arm description:

clindamycin 2-dihydrogen phosphate 1.19 %; solution

Arm type	Comparator 1 (Mono Clindamycin)
Investigational medicinal product name	Akne solution (comparator 1) mono
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

solution was applied twice daily

Arm title	Comparator 2 (mono arm)

Arm description:

sodium bituminosulfonate light 6 %; solution

Arm type	Comparator 2 (Mono Sodium bituminosulfonate light)

Investigational medicinal product name	Akne solution (comparator 2) mono
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:
Application twice daily for 12 weeks

Arm title	Comparator 3 (vehicle arm)

Arm description:
Vehicle: solution with Isopropanol

Arm type	Vehicle (solution Isopropanol)
Investigational medicinal product name	Akne solution (comparator 3) vehicle
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:
Application twice daily for 12 weeks

Number of subjects in period 1	Investigational Medicinal Product (combination arm)	Comparator 1 (mono arm)	Comparator 2 (mono arm)
Started	61	30	30
Completed	59	30	29
Not completed	2	0	1
Consent withdrawn by subject	2	-	1

Number of subjects in period 1	Comparator 3 (vehicle arm)
Started	31
Completed	30
Not completed	1
Consent withdrawn by subject	1

Baseline characteristics

Reporting groups	
Reporting group title	overall trial (overall period)

Reporting group description: -

Reporting group values	overall trial (overall period)	Total	
Number of subjects	152	152	
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)	3	3	
Adolescents (12-17 years)	98	98	
Adults (18-64 years)	51	51	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	78	78	
Male	74	74	

End points

End points reporting groups

Reporting group title	Investigational Medicinal Product (combination arm)
Reporting group description: clindamycin 2-dihydrogen phosphate 1.19 %, sodium bituminosulfonate light 6 %; solution	
Reporting group title	Comparator 1 (mono arm)
Reporting group description: clindamycin 2-dihydrogen phosphate 1.19 %; solution	
Reporting group title	Comparator 2 (mono arm)
Reporting group description: sodium bituminosulfonate light 6 %; solution	
Reporting group title	Comparator 3 (vehicle arm)
Reporting group description: Vehicle: solution with Isopropanol	

Primary: The main objective of this trial was the proof of superiority of the combination clindamycin + bituminosulfonate as compared to vehicle and to each of the mono preparations with reference to achieving success based on the GAAS.

End point title	The main objective of this trial was the proof of superiority of the combination clindamycin + bituminosulfonate as compared to vehicle and to each of the mono preparations with reference to achieving success based on the GAAS.
End point description:	
End point type	Primary
End point timeframe: considering treatment success (none or minimal acne) after 12 weeks of treatment	

End point values	Investigational Medicinal Product (combination arm)	Comparator 1 (mono arm)	Comparator 2 (mono arm)	Comparator 3 (vehicle arm)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	30	30	31
Units: GAAS (Global Acne Assessment Score)	61	30	30	31

Statistical analyses

Statistical analysis title	proof of superiority

Statistical analysis description:

The main objective of this trial was the proof of superiority of the combination clindamycin + bituminosulfonate as compared to vehicle and to each of the mono preparations with reference to achieving success based on the GAAS. Success on the 5-point scale was defined as a rating of "none" (0) or "minimal" (1) after 12 weeks.

Comparison groups	Investigational Medicinal Product (combination arm) v Comparator 1 (mono arm) v Comparator 2 (mono arm) v Comparator 3 (vehicle arm)
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.05
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Febr 2010 - Oct 2010	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.0
Reporting groups	
Reporting group title	combination arm (clindamycin+bituminosulfonate)

Reporting group description: -

Serious adverse events	combination arm (clindamycin+bitumi nosulfonate)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 61 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	combination arm (clindamycin+bitumi nosulfonate)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 61 (1.64%)		
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	3		

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