Clinical trial results:
Multi-centre, randomized, double-blind trial to compare the efficacy and safety of tretinoin clindamycin phosphate gel to clindamycin phosphate gel alone in the treatment of acne vulgaris in patients from 12 to less than 18 years of age.

Summary

EudraCT number	2010-022919-20
Trial protocol	Outside EU/EEA
Global end of trial date	01 March 2006

Results information

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

Trial information

Trial identification

Sponsor protocol code	MP-1501-02

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	1330A Redwood Way, Petaluma, United States, CA 94954-1169
Public contact	Group leader study manager, MEDA Pharma GmbH & Co. KG, +49 617288801, 42b@medapharma.de
Scientific contact	Head of Corporate Clinical Affairs, MEDA Pharma GmbH & Co. KG, +49 617288801, 42b@medapharma.de
Sponsor organisation name	Medicis Pharmaceutical Corp.
Sponsor organisation address	8125 North Hayden Road, Scottsdate, United States, AZ 85258
Public contact	Group leader study manager, Meda Pharma GmbH & Co. KG, +49 6172 888 01, 42b@medapharma.de
Scientific contact	Head of Corporate Clinical Affairs, Meda Pharma GmbH & Co. KG, +49 6172 888 01, 42b@medapharma.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000892-PIP01-10
Does article 45 of REGULATION (EC) No	Yes

1901/2006 apply to this trial?	
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	21 April 2006
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 March 2006
Global end of trial reached?	Yes
Global end of trial date	01 March 2006
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy and safety of Clin-RA Gel to Clindamycin phosphate 1.2% gel alone in the treatment of acne vulgaris.

Protection of trial subjects:

No specific additional measures to minimise pain and distress were required. The subjects could withdraw from treatment at any time and for any reason.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 September 2005
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 States: 2010
Worldwide total number of subjects	2010
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)	1320

Adults (18-64 years)	689
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Male or female subjects of any race, 12 years of age or older, with acne vulgaris, with 20 to 50 inflammatory lesions (papules and pustules), 20 to 100 noninflammatory lesions (open and closed comedones), no more than 2 nodules, and an Evaluator's Global Severity Score (EGSS) of moderate (=3) or severe (=4).

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, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Clin RA Gel

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Clindamycin phosphate 1.2% and tretinoin 0.025%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

once-a-day application (at bedtime); topically applied to the face

Arm title	Clindamycin

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Clindamycin phosphate 1.2%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

once-a-day application (at bedtime); topically applied to the face

Number of subjects in period 1	Clin RA Gel	Clindamycin
Started	1008	1002
Completed	859	838
Not completed	149	164
Consent withdrawn by subject	27	20
Adverse event, non-fatal	6	2

Other	5	3
Subject request	17	28
Lost to follow-up	92	108
Protocol deviation	1	-
Noncompliance	1	3

Baseline characteristics

Reporting groups	
Reporting group title	Clin RA Gel
Reporting group description: -	
Reporting group title	Clindamycin
Reporting group description: -	

Reporting group values	Clin RA Gel	Clindamycin	Total
Number of subjects	1008	1002	2010
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	19.1	19	
standard deviation	± 7.5	± 7	-
Gender categorical Units: Subjects			
Female	493	547	1040
Male	515	455	970

End points

End points reporting groups	
Reporting group title	Clin RA Gel
Reporting group description: -	
Reporting group title	Clindamycin
Reporting group description: -	

Primary: Dichotomized Evaluator's Global Severity Score	
End point title	Dichotomized Evaluator's Global Severity Score
End point description:	
End point type	Primary
End point timeframe:	
Baseline and week 12.	

End point values	Clin RA Gel	Clindamycin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1008	1002		
Units: Success, Failure				
Success	381	318		
Failure	627	684		

Statistical analyses

Statistical analysis title	Clin-RA vs Clindamycin
Comparison groups	Clin RA Gel v Clindamycin
Number of subjects included in analysis	2010
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Cochran-Mantel-Haenszel

Primary: Percent Change from Baseline in Inflammatory Lesion Count / Week 12	
End point title	Percent Change from Baseline in Inflammatory Lesion Count / Week 12
End point description:	
End point type	Primary

End point timeframe: Baseline and week 12.

End point values	Clin RA Gel	Clindamycin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1008	1002		
Units: percent change				
median (full range (min-max))	70 (-215.6 to 100)	64.5 (-146.4 to 100)		

Statistical analyses

Statistical analysis title	Clin-RA vs Clindamycin
Comparison groups	Clin RA Gel v Clindamycin
Number of subjects included in analysis	2010
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Primary: Percent Change from Baseline in Non-inflammatory Lesion Count / Week 12

End point title	Percent Change from Baseline in Non-inflammatory Lesion Count / Week 12
End point description:	
End point type	Primary
End point timeframe: Baseline and week 12.	

End point values	Clin RA Gel	Clindamycin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1008	1002		
Units: percent change				
median (full range (min-max))	57.6 (-157.8 to 100)	48.2 (-184.6 to 100)		

Statistical analyses

Statistical analysis title	Clin-RA vs Clindamycin
Comparison groups	Clin RA Gel v Clindamycin
Number of subjects included in analysis	2010
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Primary: Percent Change from Baseline in Total Lesion Count / Week 12

End point title	Percent Change from Baseline in Total Lesion Count / Week 12

End point description:

End point type	Primary

End point timeframe:

Baseline and week 12.

End point values	Clin RA Gel	Clindamycin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1008	1002		
Units: percent change				
median (full range (min-max))	62 (-97.4 to 100)	53.1 (-107.4 to 100)		

Statistical analyses

Statistical analysis title	Clin-RA vs Clindamycin
Comparison groups	Clin RA Gel v Clindamycin
Number of subjects included in analysis	2010
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Adverse events

Adverse events information

Timeframe for reporting adverse events:

during 12 weeks of treatment, until 30 days post-treatment

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	8.1

Reporting groups

Reporting group title	Clindamycin

Reporting group description:

Clindamycin phosphate 1.2% gel (in the same vehicle as the investigational product); once-a-day application (at bedtime); topically applied to the face

Reporting group title	Clin RA Gel

Reporting group description:

Clindamycin phosphate 1.2% and tretinoin 0.025% once-a-day application (at bedtime); topically applied to the face

Serious adverse events	Clindamycin	Clin RA Gel	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 1002 (0.30%)	2 / 1008 (0.20%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 1008 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Abdominoplasty			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 1008 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 1008 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intentional selfinjury			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 1008 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Tonsillitis			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 1008 (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: 1 %

Non-serious adverse events	Clindamycin	Clin RA Gel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	235 / 1002 (23.45%)	269 / 1008 (26.69%)	
Nervous system disorders			
Headache			
subjects affected / exposed	12 / 1002 (1.20%)	20 / 1008 (1.98%)	
occurrences (all)	12	20	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	7 / 1002 (0.70%)	11 / 1008 (1.09%)	
occurrences (all)	7	11	
Respiratory, thoracic and mediastinal disorders			
Pharyngolaryngeal pain			
subjects affected / exposed	16 / 1002 (1.60%)	19 / 1008 (1.88%)	
occurrences (all)	16	19	
Cough			
subjects affected / exposed	15 / 1002 (1.50%)	12 / 1008 (1.19%)	
occurrences (all)	15	12	
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	7 / 1002 (0.70%)	20 / 1008 (1.98%)	
occurrences (all)	7	20	
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	54 / 1002 (5.39%)	51 / 1008 (5.06%)	
occurrences (all)	54	51	
Upper respiratory tract infection			
subjects affected / exposed	17 / 1002 (1.70%)	12 / 1008 (1.19%)	
occurrences (all)	17	12	
Pharyngitis streptococcal			
subjects affected / exposed	12 / 1002 (1.20%)	9 / 1008 (0.89%)	
occurrences (all)	12	9	
Sinusitis			
subjects affected / exposed	14 / 1002 (1.40%)	12 / 1008 (1.19%)	
occurrences (all)	14	12	
Influenza			
subjects affected / exposed	7 / 1002 (0.70%)	11 / 1008 (1.09%)	
occurrences (all)	7	11	
Gastroenteritis viral			
subjects affected / exposed	11 / 1002 (1.10%)	9 / 1008 (0.89%)	
occurrences (all)	11	9	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 August 2005	Implemented changes to study procedures and analyses requested by the FDA

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported