Clinical trial results:
A Randomized, Double-Blind, Vehicle-Controlled Study Evaluating the Safety and Efficacy of IDP-109 Solution in the Treatment of Patients with Verrucae Vulgares

Summary

EudraCT number	2009-016302-16
Trial protocol	DE
Global end of trial date	25 October 2010

Results information

Result version number	v1 (current)
This version publication date	04 January 2020
First version publication date	04 January 2020

Trial information

Trial identification

Sponsor protocol code	DPSI-IDP-109-P2-01

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	1330 Redwood Way, Petaluma, United States, 947954
Public contact	Project Manager, Dow Pharmaceuticals, +1 707-793-2600,
Scientific contact	Project Manager, Dow Pharmaceuticals, +1 707-793-2600,

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	25 October 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 October 2010
Global end of trial reached?	Yes
Global end of trial date	25 October 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the safety and efficacy of once daily topical application of IDP-109 solution compared with vehicle solution in treating patients aged 18 years or older with verrucae vulgares (common warts) of the dorsal hands.

Protection of trial subjects:

The clinical trial was performed in accordance with the currently valid declaration of Helsinki as well as German regulations. The ICH guideline for GCP (January 1997) was observed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 April 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	Germany: 76
Worldwide total number of subjects	76
EEA total number of subjects	76

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)	0
Adults (18-64 years)	74
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Male or female patients of any race aged 18 years or older with common warts were eligible for this study insofar that they suffered from common warts at the dorsal hands. Safety and efficacy was expected to be similarly detectable in both males and females.

Period 1

Period 1 title	Treatment (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	IDP-109 solution

Arm description: -

Arm type	Experimental
Investigational medicinal product name	imiquimod
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Transdermal solution
Routes of administration	Topical use

Dosage and administration details:

Applied to a maximum area of 500 mm2, up to an average of 135 mg of solution/day.

Arm title	Vehicle

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Solution Vehicle
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Transdermal solution
Routes of administration	Topical use

Dosage and administration details:

Applied to a maximum area of 500 mm2, up to an average of 135 mg of solution/day.

Number of subjects in period 1	IDP-109 solution	Vehicle
Started	50	26
Completed	46	25
Not completed	4	1
Adverse event, non-fatal	1	-
Lost to follow-up	2	-

Protocol deviation	1	1

Baseline characteristics

Reporting groups	
Reporting group title	IDP-109 solution
Reporting group description: -	
Reporting group title	Vehicle
Reporting group description: -	

Reporting group values	IDP-109 solution	Vehicle	Total
Number of subjects	50	26	76
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	45.0	43.0	
standard deviation	± 16.1	± 16.2	-
Gender categorical Units: Subjects			
Female	25	12	37
Male	25	14	39
Total number of baseline warts Units: warts			
arithmetic mean	4.0	4.1	
standard deviation	± 2.08	± 2.53	-

End points

End points reporting groups	
Reporting group title	IDP-109 solution
Reporting group description: -	
Reporting group title	Vehicle
Reporting group description: -	

Primary: Complete wart clearance	
End point title	Complete wart clearance
End point description: Complete clearance was defined as resolution (0 mm² in area) of all individual baseline warts.	
End point type	Primary
End point timeframe: Week 8	

End point values	IDP-109 solution	Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	26		
Units: subjects	1	0		

Statistical analyses

Statistical analysis title	Comparison between treatment groups
Comparison groups	IDP-109 solution v Vehicle
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9082
Method	Regression, Logistic

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
8 weeks	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.0
Reporting groups	
Reporting group title	IDP-109 solution
Reporting group description: -	
Reporting group title	Vehicle
Reporting group description: -	

Serious adverse events	IDP-109 solution	Vehicle	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 50 (4.00%)	0 / 26 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Skin injury			
subjects affected / exposed	1 / 50 (2.00%)	0 / 26 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Allergic dermatits			
subjects affected / exposed	1 / 50 (2.00%)	0 / 26 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	IDP-109 solution	Vehicle	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 50 (12.00%)	5 / 26 (19.23%)	
Investigations			

Endoscopy upper gastrointestinal tract			
subjects affected / exposed	1 / 50 (2.00%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Hepatic enzyme increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
White blood cell count increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 26 (3.85%)	
occurrences (all)	0	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 50 (4.00%)	0 / 26 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Cervicobrachial syndrome			
subjects affected / exposed	0 / 50 (0.00%)	1 / 26 (3.85%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	2 / 50 (4.00%)	0 / 26 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 26 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Musculoskeletal stiffness			
subjects affected / exposed	1 / 50 (2.00%)	1 / 26 (3.85%)	
occurrences (all)	1	1	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 50 (0.00%)	2 / 26 (7.69%)	
occurrences (all)	0	2	

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