Clinical trial results:
A Multi-Center, Double-Blind, Randomized, Dose-Ranging Study of the Safety and Efficacy of IDP-102 Gel 5 %, and 15 % Compared with Vehicle in the Treatment of Common Warts.

Summary

EudraCT number	2005-002820-32
Trial protocol	DE
Global end of trial date	15 August 2006

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	250508BS

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, 94954-7121
Public contact	Project Manager, Dow Pharmaceuticals, +1 707-796-7226,
Scientific contact	Project Manager, Dow Pharmaceuticals, +1 707-796-7226,

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	15 August 2006
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 August 2006
Global end of trial reached?	Yes
Global end of trial date	15 August 2006
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To define the optimal concentration of IDP-102 Gel 5 %, and 15 % compared to vehicle when applied to common warts, for up to 12 weeks of treatment.

Protection of trial subjects:

The study was performed in accordance with the currently valid Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 December 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	Germany: 107
Worldwide total number of subjects	107
EEA total number of subjects	107

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)	107
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Males or females, aged 18 to 50 years; subjects must have been clinically diagnosed with at least 2 but not more than 15 common warts (non plantar and non-subungual). Flat warts were also excluded from treatment.

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-102 Gel 5%

Arm description: -

Arm type	Experimental
Investigational medicinal product name	IDP-102 Gel 5%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Applied topically.

Arm title	IDP-102 Gel 15%

Arm description: -

Arm type	Experimental
Investigational medicinal product name	IDP-102 Gel 15%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Applied topically.

Arm title	Vehicle Gel

Arm description: -

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

Dosage and administration details:

Applied topically.

Number of subjects in period 1	IDP-102 Gel 5%	IDP-102 Gel 15%	Vehicle Gel
Started	37	35	35
Completed	36	34	33
Not completed	1	1	2
Consent withdrawn by subject	1	-	1
Lost to follow-up	-	1	1

Baseline characteristics

Reporting groups	
Reporting group title	IDP-102 Gel 5%
Reporting group description: -	
Reporting group title	IDP-102 Gel 15%
Reporting group description: -	
Reporting group title	Vehicle Gel
Reporting group description: -	

Reporting group values	IDP-102 Gel 5%	IDP-102 Gel 15%	Vehicle Gel
Number of subjects	37	35	35
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
arithmetic mean	34.41	35.46	33.74
standard deviation	± 11.23	± 13.14	± 13.07
Gender categorical Units: Subjects			
Female	15	15	9
Male	22	20	26
Wart count Units: wart			
arithmetic mean	5.03	5.14	4.76
standard deviation	± 3.387	± 3.228	± 3.153

Reporting group values	Total		
Number of subjects	107		
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			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	39		
Male	68		
Wart count			
Units: wart			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	IDP-102 Gel 5%
Reporting group description: -	
Reporting group title	IDP-102 Gel 15%
Reporting group description: -	
Reporting group title	Vehicle Gel
Reporting group description: -	

Primary: Change from baseline in wart count

End point title	Change from baseline in wart count[1]
End point description:	
End point type	Primary
End point timeframe:	
84 days	

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 statistical comparisons were conducted between treatment groups.

End point values	IDP-102 Gel 5%	IDP-102 Gel 15%	Vehicle Gel	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	35	34	
Units: warts				
arithmetic mean (standard deviation)	0.57 (± 1.879)	0.71 (± 1.824)	0.26 (± 0.567)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 84 days	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	None
Dictionary version	NA
Reporting groups	
Reporting group title	IDP-102 Gel 5%
Reporting group description: -	
Reporting group title	IDP-102 Gel 15%
Reporting group description: -	
Reporting group title	Vehicle Gel
Reporting group description: -	

Serious adverse events	IDP-102 Gel 5%	IDP-102 Gel 15%	Vehicle Gel
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 37 (0.00%)	0 / 35 (0.00%)	0 / 34 (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: 5 %

Non-serious adverse events	IDP-102 Gel 5%	IDP-102 Gel 15%	Vehicle Gel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 37 (72.97%)	26 / 35 (74.29%)	14 / 34 (41.18%)
Investigations			
Increased GOT			
subjects affected / exposed	2 / 37 (5.41%)	0 / 35 (0.00%)	1 / 34 (2.94%)
occurrences (all)	2	0	1
Increased triglycerides			
subjects affected / exposed	2 / 37 (5.41%)	1 / 35 (2.86%)	0 / 34 (0.00%)
occurrences (all)	2	1	0
Nervous system disorders			
Headache			

subjects affected / exposed	2 / 37 (5.41%)	3 / 35 (8.57%)	3 / 34 (8.82%)
occurrences (all)	2	3	3
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 37 (0.00%)	1 / 35 (2.86%)	2 / 34 (5.88%)
occurrences (all)	0	1	2
Infections and infestations			
Cold			
subjects affected / exposed	10 / 37 (27.03%)	5 / 35 (14.29%)	5 / 34 (14.71%)
occurrences (all)	10	5	6
Hay fever			
subjects affected / exposed	1 / 37 (2.70%)	0 / 35 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	3

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 November 2005	Considering the fact that no sufficient data on reproductive toxicity are available, BfArM requested to change the wording with regards to acceptable methods of contraception to increase the safety of the patients.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported