Clinical trial results:
A comparison of the clinical efficacies of Fusidic acid hydrophilic cream 20 mg/g and Fucidin in the treatment of adult and paediatric patients with impetigo

Summary

EudraCT number	2006-002528-41
Trial protocol	NL BE
Global end of trial date	13 August 2009

Results information

Result version number	v1 (current)
This version publication date	02 January 2020
First version publication date	02 January 2020

Trial information

Trial identification

Sponsor protocol code	BPT05-641

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Interdos Pharma bv
Sponsor organisation address	Burgemeester Lemmensstraat 352, Geleen, Netherlands, 6163JT
Public contact	Jos Wesselman, Interdos, +31 882554010, j.wesselman@basicpharma.nl
Scientific contact	Jos Wesselman, Interdos, +31 882554010, j.wesselman@basicpharma.nl

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	13 August 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 August 2009
Global end of trial reached?	Yes
Global end of trial date	13 August 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The goal of this study is to assess whether the clinical efficacy and safety of Fusidic acid hydrophilic cream 20 mg/g, manufactured by Basic Pharma Manufacturing bv, and Fucidin are equivalent in a 7-day treatment of impetigo in adult and paediatric subjects.

Primary outcome: cure after 1 week. Cure is defined as the complete absence of lesions or the lesions having become dry and without crusts; remaining local erythema of the intact skin is acceptable.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 September 2006
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	Netherlands: 92
Country: Number of subjects enrolled	Belgium: 69
Country: Number of subjects enrolled	Serbia: 15
Worldwide total number of subjects	176
EEA total number of subjects	161

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)	3
Children (2-11 years)	66
Adolescents (12-17 years)	33
Adults (18-64 years)	63

From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment:
The Netherlands: 11 September 2006 - 10 April 2009
Belgium: 18 December 2007 - 23 July 2009
Serbia: 06 February 2009 - 30 July 2009

Pre-assignment

Screening details:

Not applicable. Patients with impetigo who are visiting the investigator and who comply with the inclusion criteria were be asked to participate in the study.

Period 1

Period 1 title	Overal trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Reference product (cream) was repacked in blank tubes

Arms

Are arms mutually exclusive?	Yes
Arm title	Fusidic acid hydrophilic cream 20 mg/g

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Fusidic acid hydrophilic cream 20 mg/g
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

It was not possible to establish a predefined amount of study cream that should be applied to the affected skin, because it depends on a number of variables such as number of skin lesions, size (surface area) of the lesions, location of the lesions, and age of the subject. It was left to the medical judgement of the investigator to establish the amount of cream required for a proper treatment of each patient. The investigators and patients were provided with dosing cards, adapted from the innovator's website, in order to assist the investigators in the determination and communication of the amount of study cream that should be applied, and in an effort to standardize the procedure of determining the dose of study medication.
The dose is given in terms of finger tip units. One finger tip unit is: One full finger tip of cream, this equals approximately 0.5 gram

Arm title	Fucidin® cream

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Fucidin® cream
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

It was not possible to establish a predefined amount of study cream that should be applied to the affected skin, because it depends on a number of variables such as number of skin lesions, size (surface

area) of the lesions, location of the lesions, and age of the subject. It was left to the medical judgement of the investigator to establish the amount of cream required for a proper treatment of each patient. The investigators and patients were provided with dosing cards, adapted from the innovator's website, in order to assist the investigators in the determination and communication of the amount of study cream that should be applied, and in an effort to standardize the procedure of determining the dose of study medication.
The dose is given in terms of finger tip units. One finger tip unit is: One full finger tip of cream, this equals approximately 0.5 gram

Number of subjects in period 1	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream
Started	85	91
Completed	76	81
Not completed	9	10
Treatment failure	2	-
Adverse event, non-fatal	-	2
violation inclusion criteria	-	1
Lost to follow-up	7	6
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Fusidic acid hydrophilic cream 20 mg/g
Reporting group description: -	
Reporting group title	Fucidin® cream

Reporting group description: -

Reporting group values	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream	Total
Number of subjects	85	91	176
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	1	2	3
Children (2-11 years)	34	32	66
Adolescents (12-17 years)	17	16	33
Adults (18-64 years)	27	36	63
From 65-84 years	6	5	11
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	50	42	92
Male	35	49	84

End points

End points reporting groups	
Reporting group title	Fusidic acid hydrophilic cream 20 mg/g
Reporting group description: -	
Reporting group title	Fucidin® cream
Reporting group description: -	

Primary: "cure" at week one	
End point title	"cure" at week one
End point description:	
End point type	Primary
End point timeframe: 1 week	

End point values	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	85	87		
Units: number of subjects	55	54		

Attachments (see zip file)	Cure at one week/Figure 2.jpg

Statistical analyses

Statistical analysis title	Non-inferiority analysis for "cure" at one week

Statistical analysis description:

This will be a double-blind non-inferiority trial aimed to demonstrate that the test cream is as effective the reference cream (Fucidin® cream). For this purpose it is assumed that a demonstration that 50% or more of the efficacy of fusidic acid versus placebo is maintained will suffice to accept non-inferiority. The primary efficacy analysis is the rate of "Cure" at one week. Previous studies demonstrated that with placebo the rate of cure was 13% at this point in time, versus 55% with the appl

Comparison groups	Fusidic acid hydrophilic cream 20 mg/g v Fucidin® cream
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	proportion cured at one week
Point estimate	0.975

Confidence interval	
level	95 %
sides	1-sided
lower limit	0.2

Secondary: “cure” at week two

End point title	“cure” at week two

End point description:

End point type	Secondary

End point timeframe:

2 weeks

End point values	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	85	88		
Units: number of subjects	74	77		

Attachments (see zip file)	Cure at two weeks/Figure 3.jpg

Statistical analyses

No statistical analyses for this end point

Secondary: bacterial cure at week one

End point title	bacterial cure at week one

End point description:

End point type	Secondary

End point timeframe:

1 week

End point values	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	79		
Units: number of subjects	60	62		

Statistical analyses

No statistical analyses for this end point

Secondary: bacterial cure at week two

End point title	bacterial cure at week two

End point description:

End point type	Secondary

End point timeframe:

2 weeks

End point values	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	82		
Units: number of subjects	76	77		

Statistical analyses

No statistical analyses for this end point

Secondary: "Improvement" at week one

End point title	"Improvement" at week one

End point description:

End point type	Secondary

End point timeframe:

1 week

End point values	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	85	87		
Units: number of subjects	26	29		

Statistical analyses

No statistical analyses for this end point

Secondary: "Failure" at week one

End point title	"Failure" at week one

End point description:

End point type	Secondary

End point timeframe:

1 week

End point values	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	85	87		
Units: number of subjects	4	4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

1 week, 2 weeks

Adverse event reporting additional description:

Adverse events are collected during the follow-up visits after 1 week and after 2 weeks, and reported in the Case Report Forms.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11

Reporting groups

Reporting group title	Fusidic acid hydrophilic cream 20 mg/g

Reporting group description: -

Reporting group title	Fucidin® cream

Reporting group description: -

Serious adverse events	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 85 (0.00%)	0 / 90 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Fusidic acid hydrophilic cream 20 mg/g	Fucidin® cream	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 85 (4.71%)	10 / 90 (11.11%)	
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 85 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 85 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	

Pyrexia			
subjects affected / exposed	0 / 85 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	1 / 85 (1.18%)	0 / 90 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 85 (1.18%)	0 / 90 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	1 / 85 (1.18%)	1 / 90 (1.11%)	
occurrences (all)	1	1	
Dermatitis contact			
subjects affected / exposed	1 / 85 (1.18%)	0 / 90 (0.00%)	
occurrences (all)	1	0	
Skin infection			
subjects affected / exposed	0 / 85 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	
Infections and infestations			
Lung infection			
subjects affected / exposed	0 / 85 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	
Nasopharyngitis			
subjects affected / exposed	0 / 85 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	0 / 85 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 85 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	
Cystitis			
subjects affected / exposed	0 / 85 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	

Rhinitis subjects affected / exposed occurrences (all)	0 / 85 (0.00%) 0	1 / 90 (1.11%) 1	
Metabolism and nutrition disorders Appetite disorder subjects affected / exposed occurrences (all)	0 / 85 (0.00%) 0	1 / 90 (1.11%) 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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/11809642