Clinical trial results:
Subject adherence and satisfaction for treatment of Onychomycosis with Loceryl® Nail Lacquer 5% versus Canesten® Fungal Nail Treatment Set

Summary

EudraCT number	2015-001503-31
Trial protocol	IS
Global end of trial date	14 September 2016

Results information

Result version number	v1 (current)
This version publication date	12 June 2020
First version publication date	12 June 2020

Trial information

Trial identification

Sponsor protocol code	RD.03.SPR.105078

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02705664
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GALDERMA R&D
Sponsor organisation address	Les Templiers, 2400, Route des Colles, Biot, France, 06410
Public contact	Clinical Project Manager, Galderma R&D, +33 493957051, farzaneh.sidou@galderma.com
Scientific contact	Clinical Project Manager, Galderma R&D, +33 493957051, farzaneh.sidou@galderma.com

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 March 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to compare subject-reported ease of use, adherence, and satisfaction with the following two treatments of Distal and Lateral Subungual Onychomycosis (DLSO) in toenails: Loceryl Nail Lacquer (Loceryl) and Canesten Fungal Nail Treatment Set (Urea 40% ointment and Bifonazole cream). The safety of these treatments was also evaluated.

Protection of trial subjects:

The study sponsor and any third party to whom aspects of the study management or monitoring have been delegated will undertake their assigned roles for this study in compliance with all applicable industry regulations and ICH Good Clinical Practice (GCP) Guideline E6 (1996) and EU Directive 2001/20/EC.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 January 2016
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	Iceland: 22
Worldwide total number of subjects	22
EEA total number of subjects	22

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)	16
From 65 to 84 years	6

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at a single center in Iceland between 18 January 2016 (first subject screened) to 14 September 2016 (last subject completed).

Pre-assignment

Screening details:

A total of 22 subjects with mycologically confirmed Distal and Lateral Subungual Onychomycosis (DLSO) (positive direct microscopy and culture results) were enrolled and randomized to treatment. Out of them 20 subjects had completed and 2 subjects requested early discontinued from the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Loceryl plus Canesten Fungal Nail Treatment Set

Arm description:

Each subject received 2 topical treatments with Loceryl in one foot and Canesten in the opposite foot.
Loceryl (amorolfine hydrochloride 5 percent [%]) nail lacquer was applied once weekly for 7 weeks over the great toenail of all affected toenails in the evening (at bed time).
Canesten (Urea ointment + Bifonazole cream) was applied once daily in the evening (at bedtime), in two phases: Phase 1 and Phase 2 on all affected toenails (including great toenail) of the opposite foot.
Phase I, Canesten Urea ointment was applied under occlusion for 2-3 weeks, depending on the success of removal of the diseased great toenail plates.
Phase II, Canesten Bifonazole cream was applied for 4 weeks, after the maximum 3- week treatment period with Canesten Urea ointment.
At the end of the study, subjects were provided with Loceryl at their request to complete treatment of their DLSO.

Arm type	Experimental
Investigational medicinal product name	Amorolfine Hydrochloride 5%
Investigational medicinal product code	
Other name	Loceryl®
Pharmaceutical forms	Medicated nail lacquer
Routes of administration	Topical use

Dosage and administration details:

Amorolfine hydrochloride 5 % nail lacquer was applied once weekly, topically over the entire toenail plate of all affected toenails in the evening (at bed time) for a duration of 7 weeks.

Investigational medicinal product name	Bifonazole
Investigational medicinal product code	
Other name	Canesten®
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Canesten Bifonazole cream was applied once daily over the affected toenails of opposite foot in the evening (at bed time) for 4 weeks.

Investigational medicinal product name	Urea 40%
Investigational medicinal product code	
Other name	Canesten®
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

Canesten Urea ointment was applied once daily over the affected toenails of opposite foot in the evening (at bed time) for 2-3 weeks.

Number of subjects in period 1	Loceryl plus Canesten Fungal Nail Treatment Set
Started	22
Completed	20
Not completed	2
Premature discontinuation	2

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study (overall period)

Reporting group description: -

Reporting group values	Overall Study (overall period)	Total	
Number of subjects	22	22	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 55.3 ± 12.6	 -	
Gender categorical Units: Subjects			
Female	5	5	
Male	17	17	
Race Units: Subjects			
White	22	22	

End points

End points reporting groups

Reporting group title	Loceryl plus Canesten Fungal Nail Treatment Set

Reporting group description:

Each subject received 2 topical treatments with Loceryl in one foot and Canesten in the opposite foot.
Loceryl (amorolfine hydrochloride 5 percent [%]) nail lacquer was applied once weekly for 7 weeks over the great toenail of all affected toenails in the evening (at bed time).
Canesten (Urea ointment + Bifonazole cream) was applied once daily in the evening (at bedtime), in two phases: Phase 1 and Phase 2 on all affected toenails (including great toenail) of the opposite foot.
Phase I, Canesten Urea ointment was applied under occlusion for 2-3 weeks, depending on the success of removal of the diseased great toenail plates.
Phase II, Canesten Bifonazole cream was applied for 4 weeks, after the maximum 3- week treatment period with Canesten Urea ointment.
At the end of the study, subjects were provided with Loceryl at their request to complete treatment of their DLSO.

Subject analysis set title	Loceryl
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received Amorolfine hydrochloride 5 % nail lacquer was applied once weekly, topically over the entire toenail plate of all affected toenails in the evening (at bed time) for a duration of 7

Subject analysis set title	Canesten
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subject received Canesten (Urea ointment + Bifonazole cream) was applied once daily in the evening (at bedtime), in two phases: Phase 1 and Phase 2 on all affected toenails (including great toenail) of the opposite foot.
Phase I, Canesten Urea ointment was applied under occlusion for 2-3 weeks, depending on the success of removal of the diseased great toenail plates.
Phase II, Canesten Bifonazole cream was applied for 4 weeks, after the maximum 3- week treatment period with Canesten Urea ointment

Primary: Number of Subjects who Preferred for Study Treatment at End of Phase I

End point title	Number of Subjects who Preferred for Study Treatment at End of Phase I[1]

End point description:

Number of subjects who preferred a study treatment over the other at the end of Phase 1 were reported. Intent-to-Treat (ITT) population consisted of all subjects enrolled and randomized. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

From start of study treatment up to Week 7

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: The data presented for this primary endpoint is based on a subject questionnaire regarding ease of use of the study products and satisfaction with treatment procedures. So, the statistical comparisons could not be presented.

End point values	Loceryl plus Canesten Fungal Nail Treatment Set			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Subjects				
Canesten better than Loceryl	2			

Loceryl better than Canesten	18			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects who Preferred for Study Treatment at End of Phase II

End point title	Number of Subjects who Preferred for Study Treatment at End of Phase II[2]

End point description:

Number of subjects who preferred a study treatment over the other at the end of Phase 2 were reported. ITT population consisted of all subjects enrolled and randomized. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

From start of study up to Week 7

Notes:

[2] - 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: The data presented for this primary endpoint is not analysed by the reporting arms. So, the statistical comparisons could not be presented.

End point values	Loceryl plus Canesten Fungal Nail Treatment Set			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: Subjects				
Canesten better than Loceryl	3			
Loceryl better than Canesten	18			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reported Subject Questionnaire at the End of Phase I

End point title	Number of Subjects Reported Subject Questionnaire at the End of Phase I[3]

End point description:

Subject questionnaire for the ease of use of the study products and satisfaction with treatment procedures as reported by subjects at the end of Phase I was assessed. Subject satisfaction questionnaire consisted of 12 questions (Q): Q1: How easy was it to treat your toenails, Q2: Satisfied with frequency of application, Q3: Overall, how easy to use did you find the treatment, Q4: Forgot to use it, Q5: Away from home, Q6: Did not have time to apply, Q7: Did not see any result, Q8: Grew tired of applying the treatment, Q9: Local tolerance, Q10: Procedure too difficult to follow, Q11: Local side effects further to application of the treatment, Q12: Overall, how satisfied with the treatment. ITT population consisted of all subjects enrolled and randomized. Here ‘N’ (number of subjects analyzed) signifies subjects who were evaluable for this endpoint and 'n' (number analyzed) signifies number of subjects who were evaluable for each specified category.

End point type	Primary

End point timeframe:

Week 3

Notes:

[3] - 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: The data presented for this primary endpoint is based on a subject questionnaire regarding ease of use of the study products and satisfaction with treatment procedures. So, the statistical comparisons could not be presented.

End point values	Loceryl	Canesten		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	22		
Units: Subjects				
Q1: Easy (n=22, 22)	4	6		
Q1: Fairly easy (n=22, 22)	1	10		
Q1: Not easy (n=22, 22)	1	2		
Q2: Very satisfied (n=22, 22)	16	4		
Q1: Very easy (n=22, 22)	16	4		
Q2: Satisfied (n=22, 22)	5	8		
Q2: Some what satisfied (n=22, 22)	0	6		
Q2: Not satisfied (n=22, 22)	1	4		
Q3: Very easy (n=22, 22)	15	2		
Q3: Easy (n=22, 22)	6	8		
Q3: Fairly easy (n=22, 22)	1	9		
Q3: Not easy (n=22, 22)	0	3		
Q4: No (n=9, 9)	8	7		
Q4: Yes (n=9, 9)	1	2		
Q5: No (n=9, 9)	7	5		
Q5: Yes (n=9, 9)	2	4		
Q6: No (n=9, 9)	9	6		
Q6: Yes (n=9, 9)	0	3		
Q7: No (n=9, 9)	9	9		
Q7: Yes (n=9, 9)	0	0		
Q8: No (n=9, 9)	9	7		
Q8: Yes (n=9, 9)	0	2		
Q9: No (n=9, 9)	9	8		
Q9: Yes (n=9, 9)	0	1		
Q10: No (n=9, 9)	9	7		
Q10: Yes (n=9, 9)	0	2		
Q11: Not at all (n=22, 22)	21	16		
Q11: Somewhat (n=22, 22)	1	6		
Q12: Very satisfied (n=22, 22)	13	9		
Q12: Satisfied (n=22, 22)	7	9		
Q12: Somewhat satisfied (n=22, 22)	2	3		
Q12: Notsatisfied (n=22, 22)	0	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reported Subject Questionnaire at the End of Phase II

End point title	Number of Subjects Reported Subject Questionnaire at the End of Phase II[4]

End point description:

Subject questionnaire for the ease of use of the study products and satisfaction with treatment procedures as reported by subjects at the end of Phase 2 was assessed. Subject satisfaction questionnaire consisted of 14 questions (Q): Q1: How easy was it to treat your toenails, Q2: Satisfied with frequency of application, Q3: Overall, how easy to use did you find the treatment, Q4: Forgot to use it, Q5: Away from home, Q6: Did not have time to apply, Q7: Did not see any result, Q8: Grew tired of applying the treatment, Q9: Local tolerance, Q10: Procedure too difficult to follow, Q11: Local side effects further to application of the treatment, Q12: Overall, how satisfied with the treatment, Q13: Recommend the use of study treatment, Q14: Continue to use Loceryl 7 to 10 months / Use Canesten again. ITT population was analysed. Here 'N' signifies subjects who were evaluable for this endpoint and 'n' signifies number of subjects who were evaluable for each specified category.

End point type	Primary

End point timeframe:

Week 7

Notes:

[4] - 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: The data presented for this primary endpoint is based on a subject questionnaire regarding ease of use of the study products and satisfaction with treatment procedures. So, the statistical comparisons could not be presented.

End point values	Loceryl	Canesten		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: Subjects				
Q1: Very easy (n=20, 20)	13	14		
Q1: Easy (n=20, 20)	6	3		
Q1: Fairly easy (n=20, 20)	1	2		
Q1: Not easy (n=20, 20)	0	1		
Q2: Very satisfied (n=20, 20)	14	5		
Q2: Satisfied (n=20, 20)	5	9		
Q2: Some what satisfied (n=20, 20)	1	5		
Q2: Not satisfied (n=20, 20)	0	1		
Q3: Very easy (n=20, 20)	16	8		
Q3: Easy (n=20, 20)	3	7		
Q3: Fairly easy (n=20, 20)	1	4		
Q3: Not easy (n=20, 20)	0	1		
Q4: No (n=7, 7)	6	3		
Q4: Yes (n=7, 7)	1	4		
Q5: No (n=7, 7)	3	3		
Q5: Yes (n=7, 7)	4	4		
Q6: No (n=7, 7)	7	6		
Q6: Yes (n=7, 7)	0	1		
Q7: No (n=7, 7)	7	7		
Q7: Yes (n=7, 7)	0	0		
Q8: No (n=7, 7)	7	6		
Q8: Yes (n=7, 7)	0	1		
Q9: No (n=7, 7)	7	7		
Q9: Yes (n=7, 7)	0	0		
Q10: No (n=7, 7)	7	7		

Q10: Yes (n=7, 7)	0	0		
Q11: Not at all (n=20, 20)	19	17		
Q11: Somewhat (n=20, 20)	1	3		
Q12: Very satisfied (n=20, 20)	13	8		
Q12: Satisfied (n=20, 20)	7	10		
Q12: Somewhat satisfied (n=20, 20)	0	2		
Q13: Yes (n=19, 19)	19	17		
Q13: No (n=19, 19)	0	2		
Q14: Yes (n=20, 20)	20	17		
Q13: No (n=20, 20)	0	3		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Adherence Rate to Study Product Applications

End point title	Number of Subjects with Adherence Rate to Study Product Applications[5]

End point description:

Adherence rate was subject's adherence in terms of applications was reported. ITT population consisted of all subjects enrolled and randomized.

End point type	Primary

End point timeframe:

Week 7

Notes:

[5] - 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: The data presented for this primary endpoint is not analysed by the reporting arms. So, the statistical comparisons could not be presented.

End point values	Loceryl	Canesten		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	22		
Units: Subjects				
Adherence rate: No	4	9		
Adherence rate: Yes	18	13		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Adherence Rate to Nail Preparation Procedures

End point title	Number of Subjects with Adherence Rate to Nail Preparation Procedures[6]

End point description:

Adherence rate was subject's adherence with the nail preparation procedures was reported. ITT population consisted of all subjects enrolled and randomized.

End point type	Primary

End point timeframe:

Week 3

Notes:

[6] - 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: The data presented for this primary endpoint is not analysed by the reporting arms. So, the statistical comparisons could not be presented.

End point values	Loceryl	Canesten		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	22		
Units: Subjects				
Adherence rate: No	3	17		
Adherence rate: Yes	19	5		

Statistical analyses

No statistical analyses for this end point

Primary: Local tolerance Assessment: Erythema Score at Week 7

End point title	Local tolerance Assessment: Erythema Score at Week 7[7]

End point description:

Local tolerance for erythema was assessed on the treated area at each post baseline visit. Safety population consists of the Intent-to-Treat population, after exclusion of subjects who never used the treatment with certainty based on monitoring report. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

Up to Week 7

Notes:

[7] - 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 analysis was performed for this endpoint, only descriptive analysis were reported.

End point values	Loceryl	Canesten		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	21	21		
Units: score on the scale				
arithmetic mean (standard deviation)	0.0 (± 0.0)	0.0 (± 0.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Local tolerance Assessment: Irritation Score at Week 7

End point title	Local tolerance Assessment: Irritation Score at Week 7[8]

End point description:

Local tolerance for irritation was assessed on the treated area at each post baseline visit. Safety population consists of the Intent-to-Treat population, after exclusion of subjects who never used the treatment with certainty based on monitoring report.Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

Up to Week 7

Notes:

[8] - 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 analysis was performed for this endpoint, only descriptive analysis were reported.

End point values	Loceryl	Canesten		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	21	21		
Units: score on the scale				
arithmetic mean (standard deviation)	0.0 (± 0.0)	0.0 (± 0.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Adverse Events

End point title	Number of Subjects with Adverse Events[9]

End point description:

Adverse event (AE) was any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. AE can be any unfavorable and/or unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal/investigational product, whether or not related to the medicinal/investigational products or to the study procedures.

End point type	Primary

End point timeframe:

From start of study drug administration up to Week 7

Notes:

[9] - 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 analysis was performed for this endpoint, only descriptive analysis were reported.

End point values	Loceryl plus Canesten Fungal Nail Treatment Set			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: Subjects	3			

Statistical analyses

No statistical analyses for this end point

Primary: Subjects Reported Satisfaction Questionnaire (How much time to apply treatment) at the End of Phase I

End point title	Subjects Reported Satisfaction Questionnaire (How much time to apply treatment) at the End of Phase I

End point description:

Subject questionnaire for the ease of use of the study products and satisfaction with treatment procedures as reported by subjects at the end of Phase I was assessed. Subject satisfaction questionnaire consisted of how much time to apply treatment. ITT population consisted of all subjects enrolled and randomized. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

Week 3

End point values	Loceryl	Canesten		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	22		
Units: minute				
arithmetic mean (standard deviation)	12.4 (± 7.9)	22.3 (± 8.1)		

Statistical analyses

Statistical analysis title	Loceryl Versus Canesten
Comparison groups	Loceryl v Canesten
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mcnemar

Primary: Subjects Reported Satisfaction Questionnaire (How much time to apply treatment) at the End of Phase II

End point title	Subjects Reported Satisfaction Questionnaire (How much time to apply treatment) at the End of Phase II

End point description:

Subject questionnaire for the ease of use of the study products and satisfaction with treatment procedures as reported by subjects at the end of Phase 2 was assessed. Subject satisfaction questionnaire consisted of how much time to apply treatment. ITT population consisted of all subjects enrolled and randomized. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

Week 7

End point values	Loceryl	Canesten		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: minute				
arithmetic mean (standard deviation)	10.3 (± 8.8)	7.6 (± 5.8)		

Statistical analyses

Statistical analysis title	Loceryl Versus Canesten
Comparison groups	Loceryl v Canesten
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.113
Method	Mcnemar

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From start of study drug administration up to Week 7

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18

Reporting groups

Reporting group title	All Subjects

Reporting group description:

Each subject received 2 topical treatments with Loceryl in one foot and Canesten in the opposite foot.
Loceryl (amorolfine hydrochloride 5 percent [%]) nail lacquer was applied once weekly for 7 weeks over the great toenail of all affected toenails in the evening (at bed time).
Canesten (Urea ointment + Bifonazole cream) was applied once daily in the evening (at bedtime), in two phases: Phase 1 and Phase 2 on all affected toenails (including great toenail) of the opposite foot. Phase I, Canesten Urea ointment was applied under occlusion for 2-3 weeks, depending on the success of removal of the diseased great toenail plates. Phase II, Canesten Bifonazole cream was applied for 4 weeks, after the maximum 3- week treatment period with Canesten Urea ointment.
At the end of the study, subjects was provided with Loceryl at their request to complete treatment of their DLSO.

Serious adverse events	All Subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All Subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 22 (13.64%)		
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
General disorders and administration site conditions			
Influenza like illness			

subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 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