Clinical trial results:
A randomised, double-blind, placebo-controlled phase 2 trial of FOL-005 to investigate efficacy on hair growth on scalp skin in healthy volunteers.

Summary

EudraCT number	2017-003809-17
Trial protocol	DE
Global end of trial date	22 August 2018

Results information

Result version number	v1 (current)
This version publication date	29 February 2020
First version publication date	29 February 2020

Trial information

Trial identification

Sponsor protocol code	FCS-002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03467412
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Follicum AB
Sponsor organisation address	Scheelevägen 22, LUND, Sweden, SE-223 63
Public contact	Jan Alenfall, Follicum AB, 46 709315115, jan.alenfall@follicum.com
Scientific contact	Jan Alenfall, Follicum AB, 46 709315115, jan.alenfall@follicum.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	09 July 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 August 2018
Global end of trial reached?	Yes
Global end of trial date	22 August 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of FOL-005 on scalp hair density in healthy male subjects when applied intradermally three times a week for 12 weeks.

General information:
The trial was a multicentre, randomised, double-blind, placebo-controlled phase 2 trial evaluating the efficacy, safety and tolerability of FOL-005 on scalp hair density in healthy male subjects when applied intradermally 3 times a week for 12 weeks.

The trial period consisted of a screening period of up to 3 weeks followed by 12 weeks of dosing. Each subject had 2 treatment areas evenly located on the scalp, at least 5 cm apart from each other. According to the randomisation schedule, the treatment areas were treated with either one of the following 5 treatments:
• FOL-005 0.00625 µg solution
• FOL-005 0.025 µg solution
• FOL-005 0.050 µg solution
• FOL-005 0.100 µg solution
• Placebo solution

Efficacy assessments included determination of hair growth parameters using TrichoScan imaging and measurement method

Protection of trial subjects:

The trial was conducted in compliance with the protocol, the International Conference on Harmonisation (ICH) guidelines on good clinical practice (GCP), the applicable European Directives and local legal requirements, and the ethical principles of the latest revision of the Declaration of Helsinki as adopted by the World Medical Association.
Care was taken to avoid injections on the same spot at every visit. Any AE, which brought the subject at risk would lead to treatment discontinuation.

Background therapy:

No background therapy was given.

Evidence for comparator:

No comparators were used.

Actual start date of recruitment	01 February 2018
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: 60

Worldwide total number of subjects	60
EEA total number of subjects	60

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)	60
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at 2 sites in Germany, which recruited between Feb. 2018 to May 2018. Subjects were randomized to receive 2 administrations of placebo / FOL-005 out of 5 doses of 0, 0.00625, 0.025, 0.050, and 0.100 µg FOL-005. Subjects withdrawn for IMP-unrelated reasons were to be replaced if treated for less than 4 weeks.

Pre-assignment

Screening details:

Subjects were screened for eligibility within 3 weeks of randomization. 69 subjects were screened and 9 subjects were withdrawn during the screening phase or on Day 3 (Visit 2). The reasons for withdrawal were screening failure (4), withdrawal by subject (3) and other (2). 60 subjects were randomized.

Period 1

Period 1 title	Overall Trial Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Blinding implementation details:

Solutions of different concentrations of FOL-005 and placebo were of identical appearence.
2 test areas on the subjects' scalp were randomized to receive 2 dose levels of FOL-005 or placebo (10 treatment combinations).
In order to ensure the double blindness in the trial, dilution of the IMP was done according to the trial specific laboratory manual by persons not otherwise involved in the trial.

Arms

Are arms mutually exclusive?	No
Arm title	0.00625 µg FOL-005

Arm description:

50 µL of 0.125 µg/µL (0.00625 µg) was injected intradermally into a defined treatment area on the scalp

Arm type	Experimental
Investigational medicinal product name	FOL-005 0.125 µg/µL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

50 µL solution was injected 3 times weekly for 12 weeks.

Arm title	0.025 µg FOL-005

Arm description:

50 µL of 0.5 µg/µL (0.025 µg) was injected intradermally into a defined treatment area on the scalp

Arm type	Experimental
Investigational medicinal product name	FOL-005 0.5 µg/µL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

50 µL solution was injected 3 times weekly for 12 weeks.

Arm title	0.050 µg FOL-005

Arm description:	
50 µL of 1.0 µg/µL (0.050 µg) was injected intradermally into a defined treatment area on the scalp	
Arm type	Experimental
Investigational medicinal product name	FOL-005 1.0 µg/µL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use
Dosage and administration details:	
50 µL solution was injected 3 times weekly for 12 weeks.	
Arm title	0.100 µg FOL-005
Arm description:	
50 µL of 2.0 µg/µL (0.100 µg) was injected intradermally into a defined treatment area on the scalp	
Arm type	Experimental
Investigational medicinal product name	FOL-005 2.0 µg/µL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use
Dosage and administration details:	
50 µL solution was injected 3 times weekly for 12 weeks.	
Arm title	Placebo
Arm description:	
50 µL of placebo solution was injected intradermally into a defined treatment area on the scalp	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use
Dosage and administration details:	
50 µL solution was injected 3 times weekly for 12 weeks.	

Number of subjects in period 1	0.00625 µg FOL-005	0.025 µg FOL-005	0.050 µg FOL-005
Started	25	25	25
Completed	23	24	21
Not completed	2	1	4
Consent withdrawn by subject	2	1	2
Adverse event, non-fatal	-	-	2

Number of subjects in period 1	0.100 µg FOL-005	Placebo
Started	25	20
Completed	23	17
Not completed	2	3
Consent withdrawn by subject	2	1

Adverse event, non-fatal	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial Period

Reporting group description: -

Reporting group values	Overall Trial Period	Total	
Number of subjects	60	60	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	60	60	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Healthy male subjects aged 18 - 55 years were recruited.			
Units: years			
arithmetic mean	39.4		
standard deviation	± 9.8	-	
Gender categorical			
Only male subjects were recruited.			
Units: Subjects			
Female	0	0	
Male	60	60	
Skin type (Fitzpatrick)			
Data of skin type I–IV according to Fitzpatrick’s classification were collected.			
Units: Subjects			
Type I	0	0	
Type II	12	12	
Type III	31	31	
Type IV	17	17	
Type V	0	0	
Type VI	0	0	
Weight Units: kg			
arithmetic mean	84.91		
standard deviation	± 14.88	-	
Height Units: cm			
arithmetic mean	180.6		
standard deviation	± 6.7	-	

Subject analysis sets	
Subject analysis set title	SAS
Subject analysis set type	Safety analysis
Subject analysis set description:	
All randomised subjects who received at least 1 dose of the IMP.	
Subject analysis set title	FAS
Subject analysis set type	Full analysis
Subject analysis set description:	
All correctly included (i.e. fulfilling all the entry criteria) and randomised subjects with at least 1 post-baseline measurement of the primary efficacy variable and having received at least one dose of the IMP.	
Subject analysis set title	PPS
Subject analysis set type	Per protocol
Subject analysis set description:	
All subjects included in the FAS and who had: • taken the correct treatment throughout the trial (single treatment errors were evaluated individually prior to unblinding) • no major protocol violations that could have interfered with the objectives of this trial	

Reporting group values	SAS	FAS	PPS
Number of subjects	60	58	54
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	60	58	54
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Healthy male subjects aged 18 - 55 years were recruited.			
Units: years			
arithmetic mean	39.4	39.1	39.3
standard deviation	± 9.8	± 9.7	± 10.0
Gender categorical			
Only male subjects were recruited.			
Units: Subjects			
Female	0	0	0
Male	60	58	54
Skin type (Fitzpatrick)			
Data of skin type I–IV according to Fitzpatrick’s classification were collected.			
Units: Subjects			
Type I	0	0	0
Type II	12	11	10
Type III	31	30	28
Type IV	17	17	16
Type V	0	0	0
Type VI	0	0	0

Weight			
Units: kg			
arithmetic mean	84.91	85.15	85.67
standard deviation	± 14.88	± 15.06	± 15.47
Height			
Units: cm			
arithmetic mean	180.6	180.6	180.6
standard deviation	± 6.7	± 6.8	± 7.0

End points

End points reporting groups

Reporting group title	0.00625 µg FOL-005
Reporting group description:	
50 µL of 0.125 µg/µL (0.00625 µg) was injected intradermally into a defined treatment area on the scalp	

Reporting group title	0.025 µg FOL-005
Reporting group description:	
50 µL of 0.5 µg/µL (0.025 µg) was injected intradermally into a defined treatment area on the scalp	

Reporting group title	0.050 µg FOL-005
Reporting group description:	
50 µL of 1.0 µg/µL (0.050 µg) was injected intradermally into a defined treatment area on the scalp	

Reporting group title	0.100 µg FOL-005
Reporting group description:	
50 µL of 2.0 µg/µL (0.100 µg) was injected intradermally into a defined treatment area on the scalp	

Reporting group title	Placebo
Reporting group description:	
50 µL of placebo solution was injected intradermally into a defined treatment area on the scalp	

Subject analysis set title	SAS
Subject analysis set type	Safety analysis
Subject analysis set description:	
All randomised subjects who received at least 1 dose of the IMP.	

Subject analysis set title	FAS
Subject analysis set type	Full analysis
Subject analysis set description:	
All correctly included (i.e. fulfilling all the entry criteria) and randomised subjects with at least 1 post-baseline measurement of the primary efficacy variable and having received at least one dose of the IMP.	

Subject analysis set title	PPS
Subject analysis set type	Per protocol
Subject analysis set description:	
All subjects included in the FAS and who had: • taken the correct treatment throughout the trial (single treatment errors were evaluated individually prior to unblinding) • no major protocol violations that could have interfered with the objectives of this trial	

Primary: Change in total hair density

End point title	Change in total hair density
End point description:	
Change from baseline of total hair density (number of hairs per cm2) on the scalp after 12 weeks of treatment. (Only data from subjects included in the PPS are reported.)	
End point type	Primary
End point timeframe:	
From baseline to after 12 weeks treatment	

End point values	0.00625 µg FOL-005	0.025 µg FOL-005	0.050 µg FOL-005	0.100 µg FOL-005
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	21	23
Units: hairs/cm2				
arithmetic mean (standard deviation)	1.46 (± 14.75)	2.58 (± 15.36)	-4.10 (± 21.00)	6.68 (± 22.24)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: hairs/cm2				
arithmetic mean (standard deviation)	5.60 (± 16.71)			

Statistical analyses

Statistical analysis title	Mixed effects model

Statistical analysis description:

The hypothesis that the change from baseline is equal to 0 was analysed using a mixed effects model, with baseline assessment (total hair density) and treatment-by-baseline interaction as fixed covariates, centre and treatment as fixed effects and subject as random effect. The hypothesis that the change is equal to zero was tested for each dose level separately (including placebo). The p-value and confidence interval were provided for least square mean (LSMEAN) estimates for each treatment.

Comparison groups	0.025 µg FOL-005 v 0.050 µg FOL-005 v 0.00625 µg FOL-005 v 0.100 µg FOL-005 v Placebo
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	equivalence[1]
P-value	= 0.0782 [2]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard error of the mean

Notes:

[1] - FOL-005 0.100 µg: Day 87 vs. baseline

[2] - Placebo, Day 87 vs. baseline: P-value = 0.2623
FOL-005 0.00625 µg, Day 87 vs. baseline: P-value = 0.4842
FOL-005 0.025 µg, Day 87 vs. baseline: P-value = 0.4521
FOL-005 0.050 µg, Day 87 vs. baseline: P-value = 0.5279

Secondary: Change from baseline in proportion of anagen hairs (%)

End point title	Change from baseline in proportion of anagen hairs (%)

End point description:

Change from baseline in proportion of anagen hairs (%) on the scalp after 12 weeks of treatment. (Only data from subjects included in the PPS are reported.)

End point type	Secondary

End point timeframe:

From baseline to after 12 weeks treatment

End point values	0.00625 µg FOL-005	0.025 µg FOL-005	0.050 µg FOL-005	0.100 µg FOL-005
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	21	23
Units: %				
arithmetic mean (standard deviation)	-0.03 (± 15.68)	1.40 (± 11.43)	-0.73 (± 14.23)	3.18 (± 15.16)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: %				
arithmetic mean (standard deviation)	-3.08 (± 9.53)			

Statistical analyses

Statistical analysis title	Mixed effects model

Statistical analysis description:

The hypothesis that the change from baseline is equal to 0 was analysed using a mixed effects model, with baseline assessment (% of anagen hairs) and treatment-by-baseline interaction as fixed covariates, centre and treatment as fixed effects and subject as random effect. The hypothesis that the change is equal to zero was tested for each dose level separately (including placebo). The p-value and confidence interval were provided for least square mean (LSMEAN) estimates for each treatment.

Comparison groups	0.00625 µg FOL-005 v 0.025 µg FOL-005 v 0.050 µg FOL-005 v 0.100 µg FOL-005 v Placebo
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	equivalence[3]
P-value	= 0.8025 [4]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard error of the mean

Notes:

[3] - FOL-005 0.100 µg: Day 87 vs. baseline

[4] - Placebo, Day 87 vs. baseline: P-value = 0.2140
FOL-005 0.00625 µg, Day 87 vs. baseline: P-value = 0.7312
FOL-005 0.025 µg, Day 87 vs. baseline: P-value = 0.7269
FOL-005 0.050 µg, Day 87 vs. baseline: P-value = 0.3698

Secondary: Change in proportion of telogen hairs (%)

End point title	Change in proportion of telogen hairs (%)

End point description:

Change from baseline in proportion of telogen hairs (%) on the scalp after 12 weeks of

treatment. (Only data from subjects included in the PPS are reported.)

End point type	Secondary

End point timeframe:

From baseline to after 12 weeks treatment

End point values	0.00625 µg FOL-005	0.025 µg FOL-005	0.050 µg FOL-005	0.100 µg FOL-005
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	21	23
Units: %				
arithmetic mean (standard deviation)	8.49 (± 31.36)	-0.05 (± 22.12)	8.66 (± 34.71)	2.21 (± 36.82)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: %				
arithmetic mean (standard deviation)	14.60 (± 25.58)			

Statistical analyses

Statistical analysis title	Mixed effects model

Statistical analysis description:

The hypothesis that the change from baseline is equal to 0 was analysed using a mixed effects model, with baseline assessment (% of telogen hairs) and treatment-by-baseline interaction as fixed covariates, centre and treatment as fixed effects and subject as random effect. The hypothesis that the change is equal to zero was tested for each dose level separately (including placebo). The p-value and confidence interval were provided for least square mean (LSMEAN) estimates for each treatment.

Comparison groups	0.00625 µg FOL-005 v 0.025 µg FOL-005 v 0.050 µg FOL-005 v 0.100 µg FOL-005 v Placebo
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	equivalence[5]
P-value	= 0.8025 [6]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard error of the mean

Notes:

[5] - FOL-005 0.100 µg: Day 87 vs. baseline

[6] - Placebo, Day 87 vs. baseline: P-value = 0.2140
FOL-005 0.00625 µg, Day 87 vs. baseline: P-value = 0.7312
FOL-005 0.025 µg, Day 87 vs. baseline: P-value = 0.7269

FOL-005 0.050 µg, Day 87 vs. baseline: P-value = 0.3698

Secondary: Change in anagen hair density	
End point title	Change in anagen hair density
End point description:	
Change from baseline of anagen hair density (number of hairs per cm2) on the scalp after 12 weeks of treatment. (Only data from subjects included in the PPS are reported.)	
End point type	Secondary
End point timeframe:	
From baseline to after 12 weeks treatment	

End point values	0.00625 µg FOL-005	0.025 µg FOL-005	0.050 µg FOL-005	0.100 µg FOL-005
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	21	23
Units: hairs/cm2				
arithmetic mean (standard deviation)	-2.26 (± 28.89)	3.65 (± 21.77)	-4.41 (± 24.85)	5.79 (± 25.21)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: hairs/cm2				
arithmetic mean (standard deviation)	-2.31 (± 19.70)			

Statistical analyses

Statistical analysis title	Mixed effects model
Statistical analysis description:	
The hypothesis that the change from baseline is equal to 0 was analysed using a mixed effects model, with baseline assessment (anagen hair density) and treatment-by-baseline interaction as fixed covariates, centre and treatment as fixed effects and subject as random effect. The hypothesis that the change is equal to zero was tested for each dose level separately (including placebo). The p-value and confidence interval were provided for least square mean (LSMEAN) estimates for each treatment.	
Comparison groups	0.00625 µg FOL-005 v 0.025 µg FOL-005 v 0.050 µg FOL-005 v 0.100 µg FOL-005 v Placebo
Number of subjects included in analysis	108
Analysis specification	Post-hoc
Analysis type	equivalence[7]
P-value	= 0.7768 [8]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)

Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard error of the mean

Notes:

[7] - FOL-005 0.100 µg: Day 87 vs. baseline

[8] - Placebo, Day 87 vs. baseline: P-value = 0.3875
FOL-005 0.00625 µg, Day 87 vs. baseline: P-value = 0.7660
FOL-005 0.025 µg, Day 87 vs. baseline: P-value = 0.4018
FOL-005 0.050 µg, Day 87 vs. baseline: P-value = 0.3915

Secondary: Change in telogen hair density

End point title	Change in telogen hair density

End point description:

Change from baseline of telogen hair density (number of hairs per cm2) on the scalp after 12 weeks of treatment. (Only data from subjects included in the PPS are reported.)

End point type	Secondary

End point timeframe:

From baseline to after 12 weeks treatment

End point values	0.00625 µg FOL-005	0.025 µg FOL-005	0.050 µg FOL-005	0.100 µg FOL-005
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	24	21	23
Units: hairs/cm2				
arithmetic mean (standard deviation)	3.72 (± 18.65)	-1.06 (± 16.33)	0.31 (± 16.39)	0.89 (± 22.15)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: hairs/cm2				
arithmetic mean (standard deviation)	7.91 (± 14.34)			

Statistical analyses

Statistical analysis title	Mixed effects model

Statistical analysis description:

The hypothesis that the change from baseline is equal to 0 was analysed using a mixed effects model with baseline assessment (telogen hair density) and treatment-by-baseline interaction as fixed covariates, centre and treatment as fixed effects and subject as random effect. The hypothesis that the change is equal to zero was tested for each dose level separately (including placebo). The p-value and confidence interval were provided for least square mean (LSMEAN) estimates for each treatment.

Comparison groups	0.00625 µg FOL-005 v 0.025 µg FOL-005 v 0.050 µg FOL-005 v 0.100 µg FOL-005 v Placebo

Number of subjects included in analysis	108
Analysis specification	Post-hoc
Analysis type	equivalence[9]
P-value	= 0.6676 [10]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard error of the mean

Notes:

[9] - FOL-005 0.100 µg: Day 87 vs. baseline

[10] - Placebo, Day 87 vs. baseline: P-value = 0.0708
FOL-005 0.00625 µg, Day 87 vs. baseline: P-value = 0.4005
FOL-005 0.025 µg, Day 87 vs. baseline: P-value = 0.9834
FOL-005 0.050 µg, Day 87 vs. baseline: P-value = 0.8310

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs) were collected from signing of informed consent and until end of trial.

Adverse event reporting additional description:

Both local (within 2 cm from the injection area) and non-local (all other) AEs were collected. The following AE parameters were collected:
diagnosis, start and stop dates, severity, action taken, assessment of causality, seriousness, and outcome.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Local FOL-005, 0.00625 µg

Reporting group description:

AEs appearing within 2 cm from injection site, where 0.00625 µg FOL-005 was administered.

Reporting group title	Local FOL-005, 0.025 µg

Reporting group description:

AEs appearing within 2 cm from injection site, where 0.025 µg FOL-005 was administered.

Reporting group title	Local FOL-005, 0.050 µg

Reporting group description:

AEs appearing within 2 cm from injection site, where 0.050 µg FOL-005 was administered.

Reporting group title	Local FOL-005, 0.100 µg

Reporting group description:

AEs appearing within 2 cm from injection site, where 0.100 µg FOL-005 was administered.

Reporting group title	Local Placebo

Reporting group description:

AEs appearing within 2 cm from injection site, where placebo solution was administered.

Reporting group title	Non-local FOL-005, 0.00625 µg

Reporting group description:

Subjects receiving a total dose of 0.00625 µg FOL-005

Reporting group title	Non-local FOL-005, 0.025 µg

Reporting group description:

Subjects receiving a total dose of 0.025 µg FOL-005

Reporting group title	Non-local FOL-005, 0.03125 µg

Reporting group description:

Subjects receiving a total dose of 0.03125 µg FOL-005

Reporting group title	Non-local FOL-005, 0.050 µg

Reporting group description:

Subjects receiving a total dose of 0.050 µg FOL-005

Reporting group title	Non-local FOL-005, 0.05625 µg

Reporting group description:

Subjects receiving a total dose of 0.05625 µg FOL-005

Reporting group title	Non-local FOL-005, 0.075 µg

Reporting group description:

Subjects receiving a total dose of 0.075 µg FOL-005

Reporting group title	Non-local FOL-005, 0.100 µg

Reporting group description:

Subjects receiving a total dose of 0.100 µg FOL-005

Reporting group title	Non-local FOL-005, 0.10625 µg
Reporting group description:	
Subjects receiving a total dose of 0.10625 µg FOL-005	

Reporting group title	Non-local FOL-005, 0.125 µg
Reporting group description:	
Subjects receiving a total dose of 0.125 µg FOL-005	

Reporting group title	Non-local FOL-005, 0.150 µg
Reporting group description:	
Subjects receiving a total dose of 0.150 µg FOL-005	

Serious adverse events	Local FOL-005, 0.00625 µg	Local FOL-005, 0.025 µg	Local FOL-005, 0.050 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Local FOL-005, 0.100 µg	Local Placebo	Non-local FOL-005, 0.00625 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Non-local FOL-005, 0.025 µg	Non-local FOL-005, 0.03125 µg	Non-local FOL-005, 0.050 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Non-local FOL-005, 0.05625 µg	Non-local FOL-005, 0.075 µg	Non-local FOL-005, 0.100 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Non-local FOL-005, 0.10625 µg	Non-local FOL-005, 0.125 µg	Non-local FOL-005, 0.150 µg

Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (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: 4 %

Non-serious adverse events	Local FOL-005, 0.00625 µg	Local FOL-005, 0.025 µg	Local FOL-005, 0.050 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 25 (16.00%)	8 / 25 (32.00%)	4 / 25 (16.00%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application site eczema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	2
Application site exfoliation			
subjects affected / exposed	1 / 25 (4.00%)	2 / 25 (8.00%)	2 / 25 (8.00%)
occurrences (all)	1	2	2
Fatigue			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vaccination site erythema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood glucose decreased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Urobilinogen urine increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Eye irritation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	3 / 25 (12.00%)	3 / 25 (12.00%)	1 / 25 (4.00%)
occurrences (all)	4	3	1
Skin hyperpigmentation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Application site pustules			

subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Folliculitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Gastrointestinal infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 25 (0.00%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Local FOL-005, 0.100 µg	Local Placebo	Non-local FOL-005, 0.00625 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 25 (24.00%)	5 / 20 (25.00%)	3 / 5 (60.00%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Application site eczema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Application site exfoliation			
subjects affected / exposed	2 / 25 (8.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vaccination site erythema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood glucose decreased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urobilinogen urine increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thermal burn			

subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Seborrhoeic dermatitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	4 / 25 (16.00%)	4 / 20 (20.00%)	1 / 5 (20.00%)
occurrences (all)	5	4	1
Skin hyperpigmentation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Application site pustules			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Paronychia			

subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	1 / 25 (4.00%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 25 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Non-local FOL-005, 0.025 µg	Non-local FOL-005, 0.03125 µg	Non-local FOL-005, 0.050 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 5 (80.00%)	4 / 7 (57.14%)	3 / 5 (60.00%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application site eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Application site exfoliation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaccination site erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood glucose decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Urobilinogen urine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Scratch			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Application site pustules			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gastrointestinal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 5 (20.00%)	2 / 7 (28.57%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Otitis media			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Non-local FOL-005, 0.05625 µg	Non-local FOL-005, 0.075 µg	Non-local FOL-005, 0.100 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	3 / 7 (42.86%)	3 / 5 (60.00%)

Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application site eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Application site exfoliation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Vaccination site erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood glucose decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Urobilinogen urine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Radius fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Scratch			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	2 / 7 (28.57%)	0 / 5 (0.00%)
occurrences (all)	0	5	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Eosinophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Application site pustules			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	2 / 5 (40.00%)
occurrences (all)	1	1	2
Otitis media			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Non-local FOL-005, 0.10625 µg	Non-local FOL-005, 0.125 µg	Non-local FOL-005, 0.150 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)	3 / 6 (50.00%)	5 / 7 (71.43%)
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Application site eczema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Application site exfoliation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0

Vaccination site erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood cholesterol increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood glucose decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urobilinogen urine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Thermal burn			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2

Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Application site pustules			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Otitis media			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	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