Clinical trial results:
A 16 Week, Single-Center, Randomized, Placebo- and Active-Controlled Proof-of-Principle Study to Assess the Efficacy and Safety of a 5% Minoxidil Topical Gel Formulation in Male Subjects with Androgenetic Alopecia

Summary

EudraCT number	2017-000613-22
Trial protocol	DE
Global end of trial date	05 December 2019
Results information	
Result version number	v1 (current)
This version publication date	20 December 2020
First version publication date	20 December 2020

Trial information

Trial identification	
Sponsor protocol code	CO-150225133959
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Johnson & Johnson Consumer Inc
Sponsor organisation address	199 Grandview Road, Skillman, United States, 08558
Public contact	Global Regulatory Affairs, Johnson & Johnson Consumer Inc , 215 4297845,
Scientific contact	Global Regulatory Affairs, Johnson & Johnson Consumer Inc , 215 4297845,

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	05 December 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 December 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of study was to determine the efficacy of two formulations of minoxidil, 5 percent (%) Minoxidil Topical Gel (5% MTG) and 5% Minoxidil Topical Foam (5% MTF), for hereditary hair loss in men.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices (GCP) and applicable regulatory requirements. Safety was evaluated by examining the incidence and type of adverse events, changes in clinical laboratory tests and vital signs.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 January 2019
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: 140
Worldwide total number of subjects	140
EEA total number of subjects	140

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)	140
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total of 148 subjects were screened and 140 subjects were randomized to receive one of the five study treatments.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Investigator[1]

Blinding implementation details:

Investigators were kept blinded during the study. Subjects that received gel did not know if they were on placebo or active. But subjects that received foam know they were on active.

Arms

Are arms mutually exclusive?	Yes
Arm title	5% Minoxidil Topical Gel (MTG) Once Daily (OD)

Arm description:

Subjects received 5 percent (%) MTG once daily until Week 16.

Arm type	Experimental
Investigational medicinal product name	Minoxidil Topical Gel (MTG)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Subjects received 5 percent (%) MTG once daily until Week 16.

Arm title	Placebo Topical Gel (PTG) OD

Arm description:

Subjects received matching PTG once daily until Week 16.

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

Dosage and administration details:

Subjects received matching PTG once daily until Week 16.

Arm title	5% MTG Twice a Day (BID)

Arm description:

Subjects received 5 % MTG twice daily until Week 16.

Arm type	Experimental

Investigational medicinal product name	5% MTG
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Subjects received 5% MTG twice daily until Week 16.

Arm title	PTG BID

Arm description:

Subjects received matching PTG twice daily until Week 16.

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

Dosage and administration details:

Subjects received matching PTG twice daily until Week 16.

Arm title	5% Minoxidil Topical Foam (MTF) BID

Arm description:

Subjects received 5 percent (%) MTF twice daily until Week 16.

Arm type	Active comparator
Investigational medicinal product name	5% MTF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous foam
Routes of administration	Topical use

Dosage and administration details:

Subjects received 5 percent (%) MTF twice daily until Week 16.

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Investigators were kept blinded during the study. Subjects that received gel did not know if they were on placebo or active. But subjects that received foam know they were on active.

Number of subjects in period 1	5% Minoxidil Topical Gel (MTG) Once Daily (OD)	Placebo Topical Gel (PTG) OD	5% MTG Twice a Day (BID)
Started	41	20	39
Completed	41	20	38
Not completed	0	0	1
Consent withdrawn by subject	-	-	1

Number of subjects in period 1	PTG BID	5% Minoxidil Topical Foam (MTF) BID
Started	20	20
Completed	18	19
Not completed	2	1
Consent withdrawn by subject	2	1

Baseline characteristics

Reporting groups	
Reporting group title	5% Minoxidil Topical Gel (MTG) Once Daily (OD)
Reporting group description:	
Subjects received 5 percent (%) MTG once daily until Week 16.	
Reporting group title	Placebo Topical Gel (PTG) OD
Reporting group description:	
Subjects received matching PTG once daily until Week 16.	
Reporting group title	5% MTG Twice a Day (BID)
Reporting group description:	
Subjects received 5 % MTG twice daily until Week 16.	
Reporting group title	PTG BID
Reporting group description:	
Subjects received matching PTG twice daily until Week 16.	
Reporting group title	5% Minoxidil Topical Foam (MTF) BID
Reporting group description:	
Subjects received 5 percent (%) MTF twice daily until Week 16.	

Reporting group values	5% Minoxidil Topical Gel (MTG) Once Daily (OD)	Placebo Topical Gel (PTG) OD	5% MTG Twice a Day (BID)
Number of subjects	41	20	39
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	41	20	39
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	34.1	35.2	33.3
standard deviation	± 7.69	± 6.59	± 7.82
Title for Gender Units: subjects			
Male	41	20	39

Reporting group values	PTG BID	5% Minoxidil Topical Foam (MTF) BID	Total
Number of subjects	20	20	140
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	20	20	140
From 65 to 84 years	0	0	0
85 years and over	0	0	0

Title for AgeContinuous Units: years			
arithmetic mean	32.2	32.7	
standard deviation	± 8.36	± 5.81	-
Title for Gender Units: subjects			
Male	20	20	140

End points

End points reporting groups

Reporting group title	5% Minoxidil Topical Gel (MTG) Once Daily (OD)
Reporting group description: Subjects received 5 percent (%) MTG once daily until Week 16.	
Reporting group title	Placebo Topical Gel (PTG) OD
Reporting group description: Subjects received matching PTG once daily until Week 16.	
Reporting group title	5% MTG Twice a Day (BID)
Reporting group description: Subjects received 5 % MTG twice daily until Week 16.	
Reporting group title	PTG BID
Reporting group description: Subjects received matching PTG twice daily until Week 16.	
Reporting group title	5% Minoxidil Topical Foam (MTF) BID
Reporting group description: Subjects received 5 percent (%) MTF twice daily until Week 16.	

Primary: Change from Baseline in Total Non-vellus Target Area Hair Count (TAHC) at Week 16

End point title	Change from Baseline in Total Non-vellus Target Area Hair Count (TAHC) at Week 16
End point description: TAHC was measured by computerized Hair MetrixSM system based on macrophotographs at Week 16. Intent-to-treat (ITT) population included all randomized subjects. Here, 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this endpoint.	
End point type	Primary
End point timeframe: Week 16	

End point values	5% Minoxidil Topical Gel (MTG) Once Daily (OD)	Placebo Topical Gel (PTG) OD	5% MTG Twice a Day (BID)	PTG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	20	37	20
Units: Units on a scale				
arithmetic mean (standard deviation)	29.0 (± 23.06)	8.1 (± 16.08)	43.4 (± 24.83)	0 (± 26.00)

End point values	5% Minoxidil Topical Foam (MTF) BID			
Subject group type	Reporting group			
Number of subjects analysed	19			

Units: Units on a scale				
arithmetic mean (standard deviation)	42.3 (± 40.10)			

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-20.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.59
upper limit	-6.34
Variability estimate	Standard error of the mean
Dispersion value	7.138

Statistical analysis title	Statistical Analysis 2
Comparison groups	5% MTG Twice a Day (BID) v 5% Minoxidil Topical Gel (MTG) Once Daily (OD)
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.017
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	14.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.64
upper limit	25.86
Variability estimate	Standard error of the mean
Dispersion value	5.869

Statistical analysis title	Statistical Analysis 3
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID

Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.092
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	12.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.02
upper limit	26.54
Variability estimate	Standard error of the mean
Dispersion value	7.218

Statistical analysis title	Statistical Analysis 4
Comparison groups	5% MTG Twice a Day (BID) v PTG BID
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-44.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-58.78
upper limit	-30.27
Variability estimate	Standard error of the mean
Dispersion value	7.203

Statistical analysis title	Statistical Analysis 5
Comparison groups	5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.788
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.58
upper limit	12.59

Secondary: Change from Baseline in Total Non-vellus TAHC at Weeks 8 and 12

End point title	Change from Baseline in Total Non-vellus TAHC at Weeks 8 and 12

End point description:

TAHC was measured by computerized Hair MetrixSM system based on macrophotographs at Weeks 8 and 12. ITT population included all randomized subjects. Here 'n' signifies number of subjects analyzed for specific arm.

End point type	Secondary

End point timeframe:

Weeks 8 and 12

End point values	5% Minoxidil Topical Gel (MTG) Once Daily (OD)	Placebo Topical Gel (PTG) OD	5% MTG Twice a Day (BID)	PTG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	20	39	20
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n=40, 20, 38, 18, 18))	6.9 (± 20.58)	5.9 (± 14.07)	22.0 (± 23.78)	-4.8 (± 21.16)
Week 12 (n=41, 20, 38, 18, 18)	21.8 (± 26.56)	6.3 (± 18.33)	39.2 (± 28.13)	-3.9 (± 22.17)

End point values	5% Minoxidil Topical Foam (MTF) BID			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n=40, 20, 38, 18, 18))	24.8 (± 25.33)			
Week 12 (n=41, 20, 38, 18, 18)	41.1 (± 30.66)			

Statistical analyses

Statistical analysis title	Statistical Analysis 1 (Week 8)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD

Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.919
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.48
upper limit	11.26
Variability estimate	Standard error of the mean
Dispersion value	6

Statistical analysis title	Statistical Analysis 2 (Week 8)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	14.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.14
upper limit	24.56
Variability estimate	Standard error of the mean
Dispersion value	4.906

Statistical analysis title	Statistical Analysis 3 (Week 8)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	17.83

Confidence interval	
level	95 %
sides	2-sided
lower limit	5.57
upper limit	30.09
Variability estimate	Standard error of the mean
Dispersion value	6.194

Statistical analysis title	Statistical Analysis 4 (Week 8)
Comparison groups	5% MTG Twice a Day (BID) v PTG BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-26.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.06
upper limit	-14.54
Variability estimate	Standard error of the mean
Dispersion value	6.195

Statistical analysis title	Statistical Analysis 5 (Week 8)
Comparison groups	5% Minoxidil Topical Foam (MTF) BID v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.635
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	2.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.42
upper limit	15.37
Variability estimate	Standard error of the mean
Dispersion value	6.262

Statistical analysis title	Statistical Analysis 6 (Week 12)

Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-15.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.23
upper limit	-1.16
Variability estimate	Standard error of the mean
Dispersion value	7.091

Statistical analysis title	Statistical Analysis 7 (Week 12)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	16.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.47
upper limit	28.37
Variability estimate	Standard error of the mean
Dispersion value	5.787

Statistical analysis title	Statistical Analysis 8 (Week 12)
Comparison groups	5% Minoxidil Topical Foam (MTF) BID v 5% Minoxidil Topical Gel (MTG) Once Daily (OD)
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	18.15

Confidence interval	
level	95 %
sides	2-sided
lower limit	3.67
upper limit	32.63
Variability estimate	Standard error of the mean
Dispersion value	7.32

Statistical analysis title	Statistical Analysis 9 (Week 12)
Comparison groups	PTG BID v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-43.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-58.21
upper limit	-29.12
Variability estimate	Standard error of the mean
Dispersion value	7.352

Statistical analysis title	Statistical Analysis 10 (Week 12)
Comparison groups	5% Minoxidil Topical Foam (MTF) BID v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.868
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.47
upper limit	15.94
Variability estimate	Standard error of the mean
Dispersion value	7.431

Secondary: Change from Baseline in Non-vellus Target Area Hair Width (TAHW) at

Weeks 8, 12 and 16

End point title	Change from Baseline in Non-vellus Target Area Hair Width (TAHW) at Weeks 8, 12 and 16

End point description:

TAHW was measured by computerized Hair MetrixSM system based on macrophotographs at Weeks 8, 12, and 16. ITT population included all randomized subjects. Here 'n' signifies number of subjects analyzed for specific arm.

End point type	Secondary

End point timeframe:

Weeks 8, 12 and 16

End point values	5% Minoxidil Topical Gel (MTG) Once Daily (OD)	Placebo Topical Gel (PTG) OD	5% MTG Twice a Day (BID)	PTG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	20	39	20
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n=40, 20, 38, 18, 18)	267.87 (± 1123.266)	225.98 (± 601.592)	1148.05 (± 1203.968)	-248.32 (± 1057.438)
Week 12 (n=41, 20, 38, 18, 18)	10877.12 (± 4528.346)	7992.00 (± 3978.613)	12054.63 (± 4335.559)	9623.74 (± 3166.357)
Week 16 (n=40, 20, 37, 20, 19)	1561.46 (± 1492.961)	190.30 (± 755.771)	2301.72 (± 1526.758)	-143.80 (± 1308.662)

End point values	5% Minoxidil Topical Foam (MTF) BID			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n=40, 20, 38, 18, 18)	1024.53 (± 1340.988)			
Week 12 (n=41, 20, 38, 18, 18)	10216.52 (± 4164.070)			
Week 16 (n=40, 20, 37, 20, 19)	2074.94 (± 2301.889)			

Statistical analyses

Statistical analysis title	Statistical analysis 1 (Week 8)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD

Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.96
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	15.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-591.006
upper limit	621.426
Variability estimate	Standard error of the mean
Dispersion value	306.353

Statistical analysis title	Statistical analysis 2 (Week 8)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	858.748
Confidence interval	
level	95 %
sides	2-sided
lower limit	362.76
upper limit	1354.736
Variability estimate	Standard error of the mean
Dispersion value	250.648

Statistical analysis title	Statistical analysis 3 (Week 8)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.017
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	763.563

Confidence interval	
level	95 %
sides	2-sided
lower limit	136.567
upper limit	1390.558
Variability estimate	Standard error of the mean
Dispersion value	316.853

Statistical analysis title	Statistical analysis 4 (Week 8)
Comparison groups	PTG BID v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1408.135
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2034.106
upper limit	-782.164
Variability estimate	Standard error of the mean
Dispersion value	316.335

Statistical analysis title	Statistical analysis 5 (Week 8)
Comparison groups	5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.766
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-95.185
Confidence interval	
level	95 %
sides	2-sided
lower limit	-727.523
upper limit	537.153
Variability estimate	Standard error of the mean
Dispersion value	319.553

Statistical analysis title	Statistical analysis 6 (Week 12)

Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.026
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-963.866
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1807.75
upper limit	-119.982
Variability estimate	Standard error of the mean
Dispersion value	426.49

Statistical analysis title	Statistical analysis 7 (Week 12)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	907.493
Confidence interval	
level	95 %
sides	2-sided
lower limit	218.819
upper limit	1596.167
Variability estimate	Standard error of the mean
Dispersion value	348.049

Statistical analysis title	Statistical analysis 8 (Week 12)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.102
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	725.437

Confidence interval	
level	95 %
sides	2-sided
lower limit	-147.175
upper limit	1598.049
Variability estimate	Standard error of the mean
Dispersion value	441.009

Statistical analysis title	Statistical analysis 9 (Week 12)
Comparison groups	5% MTG Twice a Day (BID) v PTG BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2514.894
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3389.491
upper limit	-1640.297
Variability estimate	Standard error of the mean
Dispersion value	442.013

Statistical analysis title	Statistical analysis 10 (Week 12)
Comparison groups	5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.684
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-182.056
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1065.551
upper limit	701.438
Variability estimate	Standard error of the mean
Dispersion value	446.509

Statistical analysis title	Statistical analysis 11 (Week 16)

Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1300.171
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2123.078
upper limit	-477.264
Variability estimate	Standard error of the mean
Dispersion value	415.95

Statistical analysis title	Statistical analysis 12 (Week 16)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.037
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	718.759
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.551
upper limit	1394.967
Variability estimate	Standard error of the mean
Dispersion value	341.799

Statistical analysis title	Statistical analysis 13 (Week 16)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.269
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	467.947

Confidence interval	
level	95 %
sides	2-sided
lower limit	-365.487
upper limit	1301.382
Variability estimate	Standard error of the mean
Dispersion value	421.271

Statistical analysis title	Statistical analysis 14 (Week 16)
Comparison groups	5% MTG Twice a Day (BID) v PTG BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2512.224
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3341.403
upper limit	-1683.045
Variability estimate	Standard error of the mean
Dispersion value	419.12

Statistical analysis title	Statistical analysis 15 (Week 16)
Comparison groups	5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.56
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-250.812
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1099.746
upper limit	598.123
Variability estimate	Standard error of the mean
Dispersion value	429.106

Secondary: Global Photographs Rating for Hair Loss Condition in the Vertex Region

at Weeks 8, 12, and 16

End point title	Global Photographs Rating for Hair Loss Condition in the Vertex Region at Weeks 8, 12, and 16

End point description:

Subject rating via global photographs of hair loss condition in the vertex region was reported at Weeks 8, 12, and 16. Hair loss condition was measured by using a 7-point scale ranging from -3 to +3: where -3 indicated significantly worse and +3 means significantly improved. ITT population included all randomized subjects. Here 'N' signifies number of subjects who were evaluable for this endpoint. Here 'n' signifies number of subjects analyzed for specific arm.

End point type	Secondary

End point timeframe:

Weeks 8, 12, and 16

End point values	5% Minoxidil Topical Gel (MTG) Once Daily (OD)	Placebo Topical Gel (PTG) OD	5% MTG Twice a Day (BID)	PTG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	20	39	20
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n=41, 20, 39, 18, 19)	0.5 (± 0.87)	0.1 (± 0.76)	0.4 (± 0.99)	0.3 (± 1.13)
Week 12 (n=41, 20, 39, 18, 19)	0.7 (± 1.02)	0.4 (± 0.88)	1.2 (± 1.11)	-0.2 (± 1.26)
Week 16 (n=41, 20, 38, 20, 20)	1.0 (± 1.08)	0.3 (± 0.73)	1.1 (± 1.17)	0.1 (± 1.02)

End point values	5% Minoxidil Topical Foam (MTF) BID			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n=41, 20, 39, 18, 19)	0.6 (± 0.90)			
Week 12 (n=41, 20, 39, 18, 19)	1.3 (± 0.75)			
Week 16 (n=41, 20, 38, 20, 20)	1.4 (± 0.75)			

Statistical analyses

Statistical analysis title	Statistical analysis 1 (Week 8)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD

Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.093
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.94
upper limit	0.07
Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	Statistical analysis 2 (Week 8)
Comparison groups	5% MTG Twice a Day (BID) v 5% Minoxidil Topical Gel (MTG) Once Daily (OD)
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.611
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	0.31
Variability estimate	Standard error of the mean
Dispersion value	0.21

Statistical analysis title	Statistical analysis 3 (Week 8)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.743
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	0.6
Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	Statistical analysis 4 (Week 8)
Comparison groups	5% MTG Twice a Day (BID) v PTG BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.683
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.64
upper limit	0.42
Variability estimate	Standard error of the mean
Dispersion value	0.27

Statistical analysis title	Statistical analysis 5 (Week 8)
Comparison groups	5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.464
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	0.71
Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	Statistical analysis 6 (Week 12)

Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.286
Method	ANCOVA
Parameter estimate	Analysis of covariance
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.86
upper limit	0.26
Variability estimate	Standard error of the mean
Dispersion value	0.28

Statistical analysis title	Statistical analysis 7 (Week 12)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.03
upper limit	0.95
Variability estimate	Standard error of the mean
Dispersion value	0.23

Statistical analysis title	Statistical analysis 8 (Week 12)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.025
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	1.22
Variability estimate	Standard error of the mean
Dispersion value	0.29

Statistical analysis title	Statistical analysis 9 (Week 12)
Comparison groups	5% MTG Twice a Day (BID) v PTG BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.96
upper limit	-0.8
Variability estimate	Standard error of the mean
Dispersion value	0.29

Statistical analysis title	Statistical analysis 10 (Week 12)
Comparison groups	5% MTG Twice a Day (BID) v 5% Minoxidil Topical Foam (MTF) BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.582
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	0.73
Variability estimate	Standard error of the mean
Dispersion value	0.29

Statistical analysis title	Statistical analysis 11 (Week 16)

Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v Placebo Topical Gel (PTG) OD
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	-0.11
Variability estimate	Standard error of the mean
Dispersion value	0.28

Statistical analysis title	Statistical analysis 12 (Week 16)
Comparison groups	5% Minoxidil Topical Gel (MTG) Once Daily (OD) v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.681
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	0.54

Statistical analysis title	Statistical analysis 13 (Week 16)
Comparison groups	5% Minoxidil Topical Foam (MTF) BID v 5% Minoxidil Topical Gel (MTG) Once Daily (OD)
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.154
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.94
Variability estimate	Standard error of the mean
Dispersion value	0.28

Statistical analysis title	Statistical analysis 14 (Week 16)
Comparison groups	5% MTG Twice a Day (BID) v PTG BID
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.56
upper limit	-0.46
Variability estimate	Standard error of the mean
Dispersion value	0.28

Statistical analysis title	Statistical analysis 15 (Week 16)
Comparison groups	5% Minoxidil Topical Foam (MTF) BID v 5% MTG Twice a Day (BID)
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.281
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.85
Variability estimate	Standard error of the mean
Dispersion value	0.28

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Approximately 1 year	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0
Reporting groups	
Reporting group title	5% MTG(OD)
Reporting group description: 5% Minoxidil Topical Gel (F13496-121) OD	
Reporting group title	PTG(OD)
Reporting group description: Placebo Topical Gel (F13496-123) OD	
Reporting group title	5% MTG(BID)
Reporting group description: 5% Minoxidil Topical Gel (F13496-121) BID	
Reporting group title	PTG(BID)
Reporting group description: Placebo Topical Gel (F13496-123) BID	
Reporting group title	5% MTF(BID)
Reporting group description: 5% Minoxidil Topical Foam (FDS-W016140-0002) BID	

Serious adverse events	5% MTG(OD)	PTG(OD)	5% MTG(BID)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PTG(BID)	5% MTF(BID)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from			

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	5% MTG(OD)	PTG(OD)	5% MTG(BID)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 41 (60.98%)	14 / 20 (70.00%)	18 / 39 (46.15%)
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Exposure to Communicable Disease			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Ligament Rupture			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Ligament Sprain			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Rib Fracture			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Scratch			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			

Angina Pectoris			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 41 (19.51%)	6 / 20 (30.00%)	3 / 39 (7.69%)
occurrences (all)	12	8	6
General disorders and administration site conditions			
Application Site Pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Application Site Pruritus			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 41 (2.44%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Food Poisoning			
subjects affected / exposed	2 / 41 (4.88%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	3	0	0
Haemorrhoids			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Toothache			

subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Rhinitis Allergic			
subjects affected / exposed	1 / 41 (2.44%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 41 (2.44%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic Dermatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Psychiatric disorders			
Sleep Disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	3 / 41 (7.32%)	1 / 20 (5.00%)	1 / 39 (2.56%)
occurrences (all)	3	1	1
Musculoskeletal Pain			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Infections and infestations			
Gastrointestinal Infection			

subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Otitis Media			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Respiratory Tract Infection			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Subcutaneous Abscess			
subjects affected / exposed	0 / 41 (0.00%)	1 / 20 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 20 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	14 / 41 (34.15%)	6 / 20 (30.00%)	10 / 39 (25.64%)
occurrences (all)	17	7	12

Non-serious adverse events	PTG(BID)	5% MTF(BID)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 20 (65.00%)	12 / 20 (60.00%)	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Exposure to Communicable Disease			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Ligament Rupture			

subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	
Ligament Sprain subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	
Rib Fracture subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	
Scratch subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1	0 / 20 (0.00%) 0	
Sunburn subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	
Cardiac disorders Angina Pectoris subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3	5 / 20 (25.00%) 13	
General disorders and administration site conditions Application Site Pain subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	1 / 20 (5.00%) 1	
Application Site Pruritus subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1	0 / 20 (0.00%) 0	
Influenza Like Illness subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	
Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1	0 / 20 (0.00%) 0	

Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Food Poisoning			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Haemorrhoids			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Rhinitis Allergic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences (all)	1	2	
Pruritus			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Seborrhoeic Dermatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Sleep Disorder			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			

Back Pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal Pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Tendonitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Gastrointestinal Infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Otitis Media			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Respiratory Tract Infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Subcutaneous Abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Viral Upper Respiratory Tract Infection			

subjects affected / exposed occurrences (all)	6 / 20 (30.00%) 6	6 / 20 (30.00%) 7	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 October 2018	Protocol Amendment-2: Protocol has been revised after comments were received from Independent Ethics Committee (IEC) in addition to some clarification added from Johnson & Johnson.
23 November 2018	Protocol Amendment 3: Protocol has been revised with some added clarifications from Johnson & Johnson as some inconsistencies were noted.
21 March 2019	Protocol Amendment 4: Protocol has been revised with some added clarifications from Johnson & Johnson as some inconsistencies were noted.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported