Clinical trial results:
A Phase 2a Randomized, Double-Blind, Placebo and Active Comparator-Controlled, Parallel Group, Dose-Range Finding Study of MVT-602 in Healthy Premenopausal Women Undergoing Controlled Ovarian Stimulation (COS) Using a Minimal Stimulation Protocol.

Summary

EudraCT number	2018-001379-20
Trial protocol	NL
Global end of trial date	11 January 2019

Results information

Result version number	v1 (current)
This version publication date	25 August 2021
First version publication date	25 August 2021

Trial information

Trial identification

Sponsor protocol code	MVT-602-009

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Myovant Sciences GmbH
Sponsor organisation address	Viaduktstrasse 8, Basel, Switzerland, 4051
Public contact	Clinical Trials, Myovant Sciences GmbH, clinicaltrials@myovant.com
Scientific contact	Elizabeth Migoya, PharmD, Myovant Sciences Inc., elizabeth.migoya@myovant.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	22 October 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 January 2019
Global end of trial reached?	Yes
Global end of trial date	11 January 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To characterize the exposure-response relationship of MVT-602 effects on luteinizing hormone (LH) concentrations after subcutaneous administration of single 0.1 to 3 micrograms (µg) doses of MVT-602, placebo, or active comparator (0.2 milligrams [mg] triptorelin) in healthy premenopausal women undergoing COS to inform dose selection of MVT-602 for subsequent studies.

Protection of trial subjects:

This study was conducted in accordance with The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which the study was conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 May 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	Netherlands: 75
Worldwide total number of subjects	75
EEA total number of subjects	75

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)	75
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Healthy adult premenopausal women were included in this study, as defined by the inclusion and exclusion criteria.

Period 1

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

Blinding implementation details:

Participants, Principal Investigator and sub-investigators, including the reproductive medicine specialist and study site staff were blinded to study treatment. Only the pharmacist and independent clinician at the study site responsible for study drug administration were unblinded. Because the injection of triptorelin (comparator) required 2 separate injections, a placebo injection was administered along with MVT-602 to keep the blind.

Arms

Are arms mutually exclusive?	Yes
Arm title	MVT-602 0.1 µg

Arm description:

Participants received a single 0.1 µg dose of MVT-602. To maintain blind, participants in the MVT-602 group also received 1 subcutaneous injection of placebo.

Arm type	Experimental
Investigational medicinal product name	MVT-602
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Injected subcutaneously as a single bolus dose.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo (glucose 5%) was administered subcutaneously.

Arm title	MVT-602 0.3 µg

Arm description:

Participants received a single 0.3 µg dose of MVT-602. To maintain blind, participants in the MVT-602 group also received 1 subcutaneous injection of placebo.

Arm type	Experimental

Investigational medicinal product name	MVT-602
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Injected subcutaneously as a single bolus dose.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo (glucose 5%) was administered subcutaneously.

Arm title	MVT-602 1 µg

Arm description:

Participants received a single 1 µg dose of MVT-602. To maintain blind, participants in the MVT-602 group also received 1 subcutaneous injection of placebo.

Arm type	Experimental
Investigational medicinal product name	MVT-602
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Injected subcutaneously as a single bolus dose.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo (glucose 5%) was administered subcutaneously.

Arm title	MVT-602 3 µg

Arm description:

Participants received a single 3 µg dose of MVT-602. To maintain blind, participants in the MVT-602 group also received 1 subcutaneous injection placebo.

Arm type	Experimental
Investigational medicinal product name	MVT-602
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Injected subcutaneously as a single bolus dose.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo (glucose 5%) was administered subcutaneously.

Arm title	Triptorelin
Arm description:	
Participants received a GnRH agonist, triptorelin 0.2 mg.	
Arm type	Active comparator
Investigational medicinal product name	Triptorelin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Triptorelin was administered as 2 separate subcutaneous injections.	

Arm title	Placebo
Arm description:	
Participants received placebo.	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Placebo (glucose 5%) was administered subcutaneously.	

Number of subjects in period 1	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg
Started	16	17	16
Received at least 1 dose of study drug	16	17	16
Completed	16	17	14
Not completed	0	0	2
Failure to meet the discharge criteria	-	-	1
Did not follow the dietary restrictions	-	-	1

Number of subjects in period 1	MVT-602 3 µg	Triptorelin	Placebo
Started	16	5	5
Received at least 1 dose of study drug	16	5	5
Completed	16	5	5
Not completed	0	0	0
Failure to meet the discharge criteria	-	-	-
Did not follow the dietary restrictions	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Overall
Reporting group description:	
All participants who received at least 1 dose of study treatment.	

Reporting group values	Overall	Total	
Number of subjects	75	75	
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)	75	75	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	25.8		
standard deviation	± 4.44	-	
Gender categorical Units: Subjects			
Female	75	75	
Male	0	0	

End points

End points reporting groups

Reporting group title	MVT-602 0.1 µg
Reporting group description:	
Participants received a single 0.1 µg dose of MVT-602. To maintain blind, participants in the MVT-602 group also received 1 subcutaneous injection of placebo.	
Reporting group title	MVT-602 0.3 µg
Reporting group description:	
Participants received a single 0.3 µg dose of MVT-602. To maintain blind, participants in the MVT-602 group also received 1 subcutaneous injection of placebo.	
Reporting group title	MVT-602 1 µg
Reporting group description:	
Participants received a single 1 µg dose of MVT-602. To maintain blind, participants in the MVT-602 group also received 1 subcutaneous injection of placebo.	
Reporting group title	MVT-602 3 µg
Reporting group description:	
Participants received a single 3 µg dose of MVT-602. To maintain blind, participants in the MVT-602 group also received 1 subcutaneous injection placebo.	
Reporting group title	Triptorelin
Reporting group description:	
Participants received a GnRH agonist, triptorelin 0.2 mg.	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo.	
Subject analysis set title	Overall
Subject analysis set type	Full analysis
Subject analysis set description:	
All participants who received at least 1 dose/injection of study treatment.	

Primary: Maximum Change From Pre-trigger LH Concentration

End point title	Maximum Change From Pre-trigger LH Concentration[1]
End point description:	
Blood samples for determination of LH concentrations were collected prior to administration of study drug and for up to 48 hours thereafter. Pre-trigger was defined as the last assessment prior to study drug administration.	
End point type	Primary
End point timeframe:	
Up to 48 hours post-trigger (study treatment)	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics are included as per protocol.

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	16
Units: U/L				
arithmetic mean (standard deviation)	62.53 (± 33.443)	76.45 (± 39.783)	70.16 (± 42.807)	82.41 (± 49.662)

End point values	Triptorelin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: U/L				
arithmetic mean (standard deviation)	184.18 (± 25.138)	34.70 (± 18.877)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline In LH Concentrations

End point title	Change From Baseline In LH Concentrations

End point description:

Blood samples for determination of pharmacodynamic endpoints were collected for up to 48 hours post-trigger administration. Baseline was defined as the assessment prior to administration of COS medication. Assessments after study treatment administration at 12, 24, 36, and 48 hours pre-discharge are presented.

End point type	Secondary

End point timeframe:

12, 24, 36, and 48 hours

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	16
Units: IU/L				
arithmetic mean (standard deviation)				
12 hour	25.04 (± 27.782)	41.29 (± 41.995)	36.41 (± 45.360)	60.41 (± 61.839)
24 hour	41.03 (± 35.003)	48.29 (± 32.426)	44.95 (± 36.955)	51.31 (± 27.953)
36 hour	19.81 (± 18.407)	26.34 (± 22.606)	32.74 (± 15.882)	38.72 (± 19.772)
48 hour	9.74 (± 8.584)	10.45 (± 11.261)	16.96 (± 13.136)	15.43 (± 10.278)

End point values	Triptorelin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: IU/L				
arithmetic mean (standard deviation)				

12 hour	176.28 (± 26.532)	4.84 (± 7.151)		
24 hour	40.06 (± 8.784)	4.70 (± 9.640)		
36 hour	17.92 (± 3.318)	20.64 (± 26.331)		
48 hour	10.98 (± 2.523)	20.82 (± 21.861)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline In Follicle Stimulating Hormone Concentrations

End point title	Change From Baseline In Follicle Stimulating Hormone Concentrations

End point description:

Blood samples for determination of follicle stimulating hormone concentrations were collected prior to administration of study drug and for up to 48 hours thereafter. Baseline was defined as the assessment prior to administration of COS medication. Assessments after study treatment administration at 12, 24, 36, and 48 hours pre-discharge are presented.

End point type	Secondary

End point timeframe:

12, 24, 36, and 48 hours

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	16
Units: IU/L				
arithmetic mean (standard deviation)				
12 hours	3.50 (± 6.576)	6.19 (± 7.522)	3.78 (± 7.227)	8.28 (± 8.949)
24 hours	7.60 (± 7.858)	9.66 (± 7.241)	6.40 (± 7.778)	10.45 (± 6.927)
36 hours	3.09 (± 5.189)	4.92 (± 4.580)	4.38 (± 4.338)	7.49 (± 5.461)
48 hours	0.26 (± 3.509)	1.72 (± 3.28)	1.50 (± 3.93)	2.19 (± 3.972)

End point values	Triptorelin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: IU/L				
arithmetic mean (standard deviation)				
12 hours	34.00 (± 8.845)	-0.96 (± 1.504)		
24 hours	12.10 (± 3.893)	-1.14 (± 2.349)		
36 hours	3.32 (± 2.461)	0.64 (± 5.740)		

48 hours	0.68 (± 2.460)	0.38 (± 5.378)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline In Estradiol Concentrations

End point title	Change From Baseline In Estradiol Concentrations

End point description:

Blood samples for determination of estradiol concentrations were collected prior to administration of study drug and for up to 48 hours thereafter. Baseline was defined as the assessment prior to administration of COS medication. Assessments after study treatment administration at 12, 24, 36, and 48 hours pre-discharge are presented.

End point type	Secondary

End point timeframe:

12, 24, 36, and 48 hours

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	16
Units: pmol/L				
arithmetic mean (standard deviation)				
12 hours	1478.7 (± 988.65)	1778.4 (± 1592.41)	1260.1 (± 630.01)	1177.8 (± 550.82)
24 hours	1431.6 (± 1105.76)	1600.6 (± 1375.02)	1363.4 (± 693.53)	1024.8 (± 439.13)
36 hours	1198.6 (± 1021.52)	1289.9 (± 1178.50)	1265.4 (± 940.60)	835.2 (± 698.81)
48 hours	886.3 (± 766.76)	859.5 (± 879.66)	1007.5 (± 806.05)	514.9 (± 640.53)

End point values	Triptorelin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: pmol/L				
arithmetic mean (standard deviation)				
12 hours	1581.2 (± 843.53)	1437.8 (± 1001.96)		
24 hours	1127.2 (± 793.99)	1825.8 (± 1444.41)		
36 hours	583.0 (± 423.07)	1998.0 (± 1545.44)		
48 hours	217.0 (± 165.60)	1891.6 (± 1509.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline In Progesterone Concentrations

End point title	Change From Baseline In Progesterone Concentrations

End point description:

Blood samples for determination of progesterone concentrations were collected prior to administration of study drug and for up to 48 hours thereafter. Baseline was defined as the assessment prior to administration of COS medication. Assessments after study treatment administration at 12, 24, 36, and 48 hours pre-discharge are presented.

End point type	Secondary

End point timeframe:

12, 24, 36, and 48 hours

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	16
Units: nmol/L				
arithmetic mean (standard deviation)				
12 hours	0.981 (± 0.5696)	1.121 (± 0.8379)	0.956 (± 0.7962)	0.877 (± 0.5295)
24 hours	1.578 (± 1.3124)	2.483 (± 2.1247)	1.604 (± 1.4307)	1.339 (± 0.7816)
36 hours	2.154 (± 1.6344)	2.416 (± 1.2955)	2.353 (± 1.2510)	1.817 (± 0.5711)
48 hours	2.193 (± 1.6848)	2.718 (± 2.0775)	2.389 (± 1.0842)	2.039 (± 1.1927)

End point values	Triptorelin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: nmol/L				
arithmetic mean (standard deviation)				
12 hours	1.650 (± 0.6078)	0.594 (± 0.3576)		
24 hours	1.330 (± 0.6061)	0.398 (± 0.4525)		
36 hours	1.530 (± 0.9041)	1.210 (± 0.9244)		
48 hours	2.410 (± 0.4036)	1.340 (± 1.2646)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time To Ovulation After Trigger Administration (Study Treatment)

End point title	Time To Ovulation After Trigger Administration (Study Treatment)

End point description:

Time ovulation (follicular rupture) as determined by transvaginal ultrasound (TVUS). Transvaginal ultrasound scans for the determination of ovulation were performed once daily (in the morning) until follicular rupture was observed or the participant met discharge criteria, which was based on initiation of menses, or estradiol or progesterone concentrations within the post-ovulatory range. Time to ovulation was defined as the time interval (in days) from the date of pre-trigger until the first date of ovulation; the censored time was the last TVUS assessment time. Time to event was analyzed using Kaplan-Meier method.

End point type	Secondary

End point timeframe:

Day 1 (after study treatment) through 13 days post discharge (-1/+3 days)

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	16
Units: days				
median (confidence interval 95%)	4.0 (4.00 to 5.00)	4.0 (4 to 4)	3.5 (3.00 to 4.00)	4 (4 to 4)

End point values	Triptorelin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: days				
median (confidence interval 95%)	4.0 (2.00 to 4.00)	5.0 (4.00 to 9.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under The Concentration-time Curve Extrapolated To Infinity (AUC0-inf)

End point title	Area Under The Concentration-time Curve Extrapolated To Infinity (AUC0-inf)[2]

End point description:

Blood samples for pharmacokinetic (PK) analysis of MVT-602 were collected up to 24 hours after administration of study treatment.

End point type	Secondary

End point timeframe:

Pre-trigger, 15 and 30 min, and 1, 2, 4, 6, 8, 12, and 24 hours post-trigger (study treatment)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only MVT-602 groups were analyzed for PK assessments.

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[3]	16	16	16
Units: pg*h/mL				
geometric mean (geometric coefficient of variation)	4.29 (± 0)	14.4 (± 18)	48.9 (± 19)	137 (± 20)

Notes:

[3] - Geometric coefficient of variation is not available since only 1 participant was analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under The Concentration-time Curve From Time Zero To Last Quantifiable Time Point (AUC0-t)

End point title	Area Under The Concentration-time Curve From Time Zero To Last Quantifiable Time Point (AUC0-t)[4]

End point description:

Blood samples for pharmacokinetic analysis of MVT-602 were collected up to 24 hours after administration of study treatment.

End point type	Secondary

End point timeframe:

Pre-trigger, 15 and 30 min, and 1, 2, 4, 6, 8, 12, and 24 hours post-trigger (study treatment)

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only MVT-602 groups were analyzed for PK assessments.

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	16
Units: pg*h/mL				
geometric mean (geometric coefficient of variation)	3.69 (± 12)	12.7 (± 19)	46.9 (± 19)	134 (± 20)

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Concentration (Cmax)

End point title	Maximum Concentration (Cmax)[5]

End point description:

Blood samples for pharmacokinetic analysis of MVT-602 were collected up to 24 hours after administration of study treatment.

End point type	Secondary

End point timeframe:

Pre-trigger, 15 and 30 min, and 1, 2, 4, 6, 8, 12, and 24 hours post-trigger (study treatment)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only MVT-602 groups were analyzed for PK assessments.

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	16
Units: pg/mL				
geometric mean (geometric coefficient of variation)	3.03 (± 21)	6.86 (± 34)	22.9 (± 24)	63.1 (± 32)

Statistical analyses

No statistical analyses for this end point

Secondary: Time To Maximum Concentration (tmax)

End point title	Time To Maximum Concentration (tmax)[6]

End point description:

Blood samples for pharmacokinetic analysis of MVT-602 were collected up to 24 hours after administration of study treatment.

End point type	Secondary

End point timeframe:

Pre-trigger, 15 and 30 min, and 1, 2, 4, 6, 8, 12, and 24 hours post-trigger (study treatment)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only MVT-602 groups were analyzed for PK assessments.

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	16
Units: hour				
median (full range (min-max))	0.26 (0.25 to 1.00)	0.50 (0.25 to 1.00)	0.50 (0.25 to 1.00)	0.50 (0.25 to 1.03)

Statistical analyses

No statistical analyses for this end point

Secondary: Elimination Half-life (t1/2)

End point title	Elimination Half-life (t1/2)[7]

End point description:

Blood samples for pharmacokinetic analysis of MVT-602 were collected up to 24 hours after administration of study treatment.

End point type	Secondary

End point timeframe:

Pre-trigger, 15 and 30 min, and 1, 2, 4, 6, 8, 12, and 24 hours post-trigger (study treatment)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only MVT-602 groups were analyzed for PK assessments.

End point values	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg	MVT-602 3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[8]	16	16	16
Units: hour				
geometric mean (geometric coefficient of variation)	0.602 (± 0)	1.26 (± 19)	1.85 (± 23)	2.03 (± 26)

Notes:

[8] - Geometric coefficient of variation is not available since only 1 participant was analyzed.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Day 1 (after study treatment) through 13 days post discharge (-1/+3 days).	
Adverse event reporting additional description:	
All participants who received at least 1 dose of study treatment.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups	
Reporting group title	MVT-602 0.1 µg
Reporting group description:	
Participants received a single 0.1 µg dose of MVT-602.	
Reporting group title	MVT-602 0.3 µg
Reporting group description:	
Participants received a single 0.3 µg dose of MVT-602.	
Reporting group title	MVT-602 1 µg
Reporting group description:	
Participants received a single 1 µg dose of MVT-602.	
Reporting group title	MVT-602 3 µg
Reporting group description:	
Participants received a single 3 µg dose of MVT-602.	
Reporting group title	Triptorelin
Reporting group description:	
Participants received a GnRH agonist, triptorelin 0.2 mg.	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo.	
Reporting group title	Overall
Reporting group description:	
All participants who received at least 1 dose/injection of study treatment.	

Serious adverse events	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	MVT-602 3 µg	Triptorelin	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (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	Overall		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 75 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 4 %

Non-serious adverse events	MVT-602 0.1 µg	MVT-602 0.3 µg	MVT-602 1 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 16 (93.75%)	17 / 17 (100.00%)	15 / 16 (93.75%)
Vascular disorders			
Orthostatic hypotension			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Administration site discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	2 / 16 (12.50%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Catheter site related reaction			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	1 / 16 (6.25%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Fatigue			

subjects affected / exposed	3 / 16 (18.75%)	2 / 17 (11.76%)	1 / 16 (6.25%)
occurrences (all)	3	3	1
Feeling hot			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Injection site bruising			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Injection site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Injection site pruritus			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			
subjects affected / exposed	1 / 16 (6.25%)	2 / 17 (11.76%)	2 / 16 (12.50%)
occurrences (all)	1	2	2
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Dysmenorrhoea			
subjects affected / exposed	2 / 16 (12.50%)	2 / 17 (11.76%)	0 / 16 (0.00%)
occurrences (all)	2	2	0
Menorrhagia			

subjects affected / exposed	1 / 16 (6.25%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Nipple pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Ovarian cyst			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Pelvic discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	1 / 16 (6.25%)
occurrences (all)	0	1	2
Polycystic ovaries			
subjects affected / exposed	0 / 16 (0.00%)	3 / 17 (17.65%)	0 / 16 (0.00%)
occurrences (all)	0	3	0
Vaginal discharge			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	2 / 16 (12.50%)
occurrences (all)	1	0	2
Vaginal haemorrhage			
subjects affected / exposed	1 / 16 (6.25%)	2 / 17 (11.76%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Epistaxis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			

Insomnia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Mood altered			
subjects affected / exposed	0 / 16 (0.00%)	2 / 17 (11.76%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Nightmare			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Oestradiol increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 16 (25.00%)	3 / 17 (17.65%)	3 / 16 (18.75%)
occurrences (all)	4	3	6
Dizziness postural			
subjects affected / exposed	2 / 16 (12.50%)	0 / 17 (0.00%)	2 / 16 (12.50%)
occurrences (all)	3	0	2
Dysgeusia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 17 (11.76%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Head discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Sensory disturbance			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	5 / 16 (31.25%)	9 / 17 (52.94%)	7 / 16 (43.75%)
occurrences (all)	13	14	11
Ear and labyrinth disorders			
Excessive cerumen production			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Motion sickness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Eye disorders			
Eye allergy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Eyelid irritation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	3 / 16 (18.75%)
occurrences (all)	1	0	3
Abdominal distension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	2 / 16 (12.50%)	5 / 17 (29.41%)	4 / 16 (25.00%)
occurrences (all)	2	6	4
Abdominal pain lower			
subjects affected / exposed	1 / 16 (6.25%)	1 / 17 (5.88%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Abdominal pain upper			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 16 (6.25%)	1 / 17 (5.88%)	2 / 16 (12.50%)
occurrences (all)	1	1	2
Nausea			
subjects affected / exposed	1 / 16 (6.25%)	2 / 17 (11.76%)	2 / 16 (12.50%)
occurrences (all)	1	2	3
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	1 / 16 (6.25%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 17 (11.76%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Neck pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Folliculitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	1 / 17 (5.88%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Oral herpes			
subjects affected / exposed	2 / 16 (12.50%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Otitis externa			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	MVT-602 3 µg	Triptorelin	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 16 (93.75%)	2 / 5 (40.00%)	5 / 5 (100.00%)
Vascular disorders			
Orthostatic hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Administration site discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Catheter site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Catheter site related reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 16 (12.50%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Feeling hot			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Injection site bruising			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	2 / 16 (12.50%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Menorrhagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nipple pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Polycystic ovaries			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vaginal discharge			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	3 / 16 (18.75%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Nightmare			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oestradiol increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 16 (25.00%)	2 / 5 (40.00%)	1 / 5 (20.00%)
occurrences (all)	4	6	1
Dizziness postural			
subjects affected / exposed	3 / 16 (18.75%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Dysgeusia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Restless legs syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	7 / 16 (43.75%)	1 / 5 (20.00%)	2 / 5 (40.00%)
occurrences (all)	10	1	2
Ear and labyrinth disorders			
Excessive cerumen production			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Motion sickness			

subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Eye allergy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Eye irritation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eyelid irritation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	3 / 16 (18.75%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	5	0	0
Abdominal pain			
subjects affected / exposed	3 / 16 (18.75%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	4	0	3
Abdominal pain lower			
subjects affected / exposed	1 / 16 (6.25%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	2 / 16 (12.50%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Nausea			

subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 16 (18.75%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	3	1	0
Myalgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Folliculitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Otitis externa			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Overall		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	69 / 75 (92.00%)		
Vascular disorders			
Orthostatic hypotension			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
General disorders and administration site conditions			
Administration site discomfort			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Catheter site pain			
subjects affected / exposed	3 / 75 (4.00%)		
occurrences (all)	3		
Catheter site related reaction			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Chest discomfort			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Chest pain			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	8 / 75 (10.67%)		
occurrences (all)	10		

Feeling hot			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Influenza like illness			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Injection site bruising			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Injection site hypersensitivity			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Injection site pain			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Injection site pruritus			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Injection site reaction			
subjects affected / exposed	7 / 75 (9.33%)		
occurrences (all)	7		
Pain			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Dysmenorrhoea			
subjects affected / exposed	4 / 75 (5.33%)		
occurrences (all)	4		
Menorrhagia			
subjects affected / exposed	3 / 75 (4.00%)		
occurrences (all)	3		
Nipple pain			

subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Ovarian cyst			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Pelvic discomfort			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	3		
Polycystic ovaries			
subjects affected / exposed	4 / 75 (5.33%)		
occurrences (all)	4		
Vaginal discharge			
subjects affected / exposed	3 / 75 (4.00%)		
occurrences (all)	3		
Vaginal haemorrhage			
subjects affected / exposed	3 / 75 (4.00%)		
occurrences (all)	3		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Epistaxis			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	4 / 75 (5.33%)		
occurrences (all)	4		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Mood altered			

subjects affected / exposed	4 / 75 (5.33%)		
occurrences (all)	4		
Nightmare			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	3		
Oestradiol increased			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Nervous system disorders			
Dizziness			
subjects affected / exposed	17 / 75 (22.67%)		
occurrences (all)	24		
Dizziness postural			
subjects affected / exposed	7 / 75 (9.33%)		
occurrences (all)	8		
Dysgeusia			
subjects affected / exposed	3 / 75 (4.00%)		
occurrences (all)	3		
Head discomfort			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	3		
Hypoaesthesia			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Paraesthesia			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Restless legs syndrome			

subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Sensory disturbance			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Somnolence			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	31 / 75 (41.33%)		
occurrences (all)	51		
Ear and labyrinth disorders			
Excessive cerumen production			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Motion sickness			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Eye disorders			
Eye allergy			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Eye irritation			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Eyelid irritation			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Ocular hyperaemia			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	4 / 75 (5.33%)		
occurrences (all)	4		
Abdominal distension			

subjects affected / exposed	5 / 75 (6.67%)		
occurrences (all)	7		
Abdominal pain			
subjects affected / exposed	16 / 75 (21.33%)		
occurrences (all)	19		
Abdominal pain lower			
subjects affected / exposed	5 / 75 (6.67%)		
occurrences (all)	5		
Abdominal pain upper			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	6 / 75 (8.00%)		
occurrences (all)	6		
Nausea			
subjects affected / exposed	6 / 75 (8.00%)		
occurrences (all)	7		
Vomiting			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Dysuria			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	6 / 75 (8.00%)		
occurrences (all)	6		
Myalgia			

subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Neck pain			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Infections and infestations			
Folliculitis			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	3 / 75 (4.00%)		
occurrences (all)	3		
Oral herpes			
subjects affected / exposed	3 / 75 (4.00%)		
occurrences (all)	3		
Otitis externa			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	2 / 75 (2.67%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 75 (1.33%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 April 2018	- Exclusion Criteria # 14 was amended to include the use of an injectable hormonal method of contraception within 6 months prior to Day 1 in the Run-in Period. - Clarified Section 5.6.1 Synchronization Screen Failure. - Clarified Section 5.6.2 Run-in Screen Failure. - Revised the risk assessment and mitigation strategy for MVT-602 to include all monitoring timepoints for Reproductive Toxicity.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None

Notes: