



Clinical trial results:

A Safety, Tolerability and Pharmacokinetic Study of Tirzepatide for the Treatment of Pediatric Participants (6 years to 11 years) with Obesity.

Summary

EudraCT number	2024-000081-22
Trial protocol	Outside EU/EEA
Global end of trial date	16 January 2025

Results information

Result version number	v1 (current)
This version publication date	31 July 2025
First version publication date	31 July 2025

Trial information

Trial identification

Sponsor protocol code	I8F-MC-GPHV
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05696847
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Clinical Trial Registry Office, Eli Lilly and Company, 1 877 CTLilly, EU_Lilly_Clinical_Trials@lilly.com
Scientific contact	Clinical Trial Registry Office, Eli Lilly and Company, 1 877285 4559, EU_Lilly_Clinical_Trials@lilly.com
Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly, ClinicalTrials.gov@lilly.com
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559, ClinicalTrials.gov@lilly.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-002360-PIP02-22
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	16 January 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	16 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs)

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (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 a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 February 2023
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	United States: 28
Worldwide total number of subjects	28
EEA total number of subjects	0

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)	28
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

NA

Pre-assignment

Screening details:

NA

Period 1

Period 1 title	Screening Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: Placebo (BW \geq 50 kg)

Arm description:

Participants in this cohort had a screening body weight (BW) of at least 50 kilograms (kg) received placebo administered subcutaneously (SC) once weekly (QW) during Weeks 1 to 8.

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:

Administered subcutaneously.

Arm title	Cohort 1: 2.5-5 mg Tirzepatide (BW \geq 50 kg)
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Arm description:

Participants in this cohort had a screening body weight of at least 50 kg, received 2.5 milligrams (mg) tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.

Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	
Other name	LY3298176
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered subcutaneously.

Arm title	Cohort 2: Placebo (BW $<$ 50 kg)
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Arm description:

Participants in this cohort had a screening body weight less than 50 kg, received placebo administered SC QW during Weeks 1 to 8.

Arm type	Placebo
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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:	
Administered subcutaneously.	
Arm title	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)
Arm description:	
Participants in this cohort had a screening body weight less than 50 kg received 1.25 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 2.5 mg tirzepatide during Weeks 5 to 8.	
Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	
Other name	LY3298176
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered subcutaneously.	
Arm title	Cohort 3: Placebo (BW 40 to 60 kg)
Arm description:	
Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received placebo administered SC QW during Weeks 1 to 8.	
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:	
Administered subcutaneously.	
Arm title	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)
Arm description:	
Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received 2.5 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.	
Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	
Other name	LY3298176
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered subcutaneously.	

Number of subjects in period 1	Cohort 1: Placebo (BW ≥50 kg)	Cohort 1: 2.5-5 mg Tirzepatide (BW ≥50 kg)	Cohort 2: Placebo (BW <50 kg)
Started	3	6	2
Completed	2	6	2
Not completed	1	0	0
Consent withdrawn by subject	1	-	-

Number of subjects in period 1	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)	Cohort 3: Placebo (BW 40 to 60 kg)	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)
Started	7	3	7
Completed	7	3	7
Not completed	0	0	0
Consent withdrawn by subject	-	-	-

Period 2

Period 2 title	Treatment Period
Is this the baseline period?	Yes ^[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: Placebo (BW ≥50 kg)

Arm description:

Participants in this cohort had a screening body weight (BW) of at least 50 kilograms (kg) received placebo administered subcutaneously (SC) once weekly (QW) during Weeks 1 to 8.

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:

Administered subcutaneously.

Arm title	Cohort 1: 2.5-5 mg Tirzepatide (BW ≥50 kg)
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Arm description:

Participants in this cohort had a screening body weight of at least 50 kg received 2.5 milligrams (mg) tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.

Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	
Other name	LY3298176
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered subcutaneously.

Arm title	Cohort 2: Placebo (BW <50 kg)
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Arm description:

Participants in this cohort had a screening body weight less than 50 kg received placebo administered SC QW during Weeks 1 to 8.

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:
Administered subcutaneously.

Arm title	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)
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Arm description:

Participants in this cohort had a screening body weight less than 50 kg received 1.25 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 2.5 mg tirzepatide during Weeks 5 to 8.

Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	
Other name	LY3298176
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered subcutaneously.

Arm title	Cohort 3: Placebo (BW 40 to 60 kg)
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Arm description:

Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received placebo administered SC QW during Weeks 1 to 8.

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:
Administered subcutaneously.

Arm title	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)
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Arm description:

Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received 2.5 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.

Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	
Other name	LY3298176
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered subcutaneously.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Period 1 was only screening period and not the baseline period. Period 2 (Treatment Period) was added as the baseline period per planned analysis.

Number of subjects in period 2 ^[2]	Cohort 1: Placebo (BW ≥50 kg)	Cohort 1: 2.5-5 mg Tirzepatide (BW ≥50 kg)	Cohort 2: Placebo (BW <50 kg)
Started	2	6	2
Received At Least One Dose of Study Drug	2	6	2
Completed	2	5	2
Not completed	0	1	0
Adverse event, non-fatal	-	-	-
Withdrawal by Parent/Guardian	-	1	-
Sponsor Decision	-	-	-

Number of subjects in period 2 ^[2]	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)	Cohort 3: Placebo (BW 40 to 60 kg)	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)
Started	7	3	7
Received At Least One Dose of Study Drug	7	3	7
Completed	6	3	6
Not completed	1	0	1
Adverse event, non-fatal	-	-	1
Withdrawal by Parent/Guardian	-	-	-
Sponsor Decision	1	-	-

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Subjects reported in treatment period (considered as baseline period) are 27. 1 subject from the 28 enrolled subjects, discontinued the study in the screening period prior to receiving any treatment and was not included in the treatment period.

Baseline characteristics

Reporting groups

Reporting group title	Cohort 1: Placebo (BW \geq 50 kg)
Reporting group description: Participants in this cohort had a screening body weight (BW) of at least 50 kilograms (kg) received placebo administered subcutaneously (SC) once weekly (QW) during Weeks 1 to 8.	
Reporting group title	Cohort 1: 2.5-5 mg Tirzepatide (BW \geq 50 kg)
Reporting group description: Participants in this cohort had a screening body weight of at least 50 kg received 2.5 milligrams (mg) tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.	
Reporting group title	Cohort 2: Placebo (BW <50 kg)
Reporting group description: Participants in this cohort had a screening body weight less than 50 kg received placebo administered SC QW during Weeks 1 to 8.	
Reporting group title	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)
Reporting group description: Participants in this cohort had a screening body weight less than 50 kg received 1.25 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 2.5 mg tirzepatide during Weeks 5 to 8.	
Reporting group title	Cohort 3: Placebo (BW 40 to 60 kg)
Reporting group description: Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received placebo administered SC QW during Weeks 1 to 8.	
Reporting group title	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)
Reporting group description: Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received 2.5 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.	

Reporting group values	Cohort 1: Placebo (BW \geq 50 kg)	Cohort 1: 2.5-5 mg Tirzepatide (BW \geq 50 kg)	Cohort 2: Placebo (BW <50 kg)
Number of subjects	2	6	2
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	2	6	2
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	1	3	2
Male	1	3	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0

Not Hispanic or Latino	2	5	2
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islande	0	0	0
Black or African American	1	4	2
White	1	2	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment			
Units: Subjects			
United States	2	6	2

Reporting group values	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)	Cohort 3: Placebo (BW 40 to 60 kg)	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)
Number of subjects	7	3	7
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	7	3	7
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	5	2	4
Male	2	1	3
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	0	2
Not Hispanic or Latino	5	3	5
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islande	0	0	0
Black or African American	2	1	4
White	5	2	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment			

Units: Subjects			
United States	7	3	7

Reporting group values	Total		
Number of subjects	27		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	27		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Gender categorical			
Units: Subjects			
Female	17		
Male	10		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	5		
Not Hispanic or Latino	22		
Unknown or Not Reported	0		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0		
Asian	0		
Native Hawaiian or Other Pacific Islande	0		
Black or African American	14		
White	13		
More than one race	0		
Unknown or Not Reported	0		
Region of Enrollment			
Units: Subjects			
United States	27		

End points

End points reporting groups

Reporting group title	Cohort 1: Placebo (BW ≥50 kg)
Reporting group description: Participants in this cohort had a screening body weight (BW) of at least 50 kilograms (kg) received placebo administered subcutaneously (SC) once weekly (QW) during Weeks 1 to 8.	
Reporting group title	Cohort 1: 2.5-5 mg Tirzepatide (BW ≥50 kg)
Reporting group description: Participants in this cohort had a screening body weight of at least 50 kg, received 2.5 milligrams (mg) tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.	
Reporting group title	Cohort 2: Placebo (BW <50 kg)
Reporting group description: Participants in this cohort had a screening body weight less than 50 kg, received placebo administered SC QW during Weeks 1 to 8.	
Reporting group title	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)
Reporting group description: Participants in this cohort had a screening body weight less than 50 kg received 1.25 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 2.5 mg tirzepatide during Weeks 5 to 8.	
Reporting group title	Cohort 3: Placebo (BW 40 to 60 kg)
Reporting group description: Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received placebo administered SC QW during Weeks 1 to 8.	
Reporting group title	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)
Reporting group description: Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received 2.5 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.	
Reporting group title	Cohort 1: Placebo (BW ≥50 kg)
Reporting group description: Participants in this cohort had a screening body weight (BW) of at least 50 kilograms (kg) received placebo administered subcutaneously (SC) once weekly (QW) during Weeks 1 to 8.	
Reporting group title	Cohort 1: 2.5-5 mg Tirzepatide (BW ≥50 kg)
Reporting group description: Participants in this cohort had a screening body weight of at least 50 kg received 2.5 milligrams (mg) tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.	
Reporting group title	Cohort 2: Placebo (BW <50 kg)
Reporting group description: Participants in this cohort had a screening body weight less than 50 kg received placebo administered SC QW during Weeks 1 to 8.	
Reporting group title	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)
Reporting group description: Participants in this cohort had a screening body weight less than 50 kg received 1.25 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 2.5 mg tirzepatide during Weeks 5 to 8.	
Reporting group title	Cohort 3: Placebo (BW 40 to 60 kg)
Reporting group description: Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received placebo administered SC QW during Weeks 1 to 8.	
Reporting group title	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)
Reporting group description: Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received 2.5 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.	

Primary: Percentage of Participants With One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs)

End point title	Percentage of Participants With One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) ^[1]
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End point description:

Percentage of participants with TEAEs and SAEs were reported here. A summary of TEAEs, SAEs and other non-serious adverse events, regardless of causality, is reported in the Reported Adverse Events section in this record.

Analysis Population Description (APD): All participants who received at least one dose of study drug.

End point type	Primary
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End point timeframe:

Baseline Up To 14 Weeks

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: No inferential statistics was planned for this end point.

End point values	Cohort 1: Placebo (BW ≥50 kg)	Cohort 1: 2.5-5 mg Tirzepatide (BW ≥50 kg)	Cohort 2: Placebo (BW <50 kg)	Cohort 2: 1.25- 2.5 mg Tirzepatide (BW <50 kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	6	2	7
Units: Percentage of Participants				
number (not applicable)				
TEAE	0	83.3	0	85.7
SAE	0	0	0	0

End point values	Cohort 3: Placebo (BW 40 to 60 kg)	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: Percentage of Participants				
number (not applicable)				
TEAE	33.3	100		
SAE	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve From Time 0 to the End of the Dosing Interval (AUC0-tau) of Tirzepatide

End point title	Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve From Time 0 to the End of the Dosing Interval (AUC0-tau) of Tirzepatide ^[2]
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End point description:

PK: AUC0-tau of tirzepatide

APD: All participants who received at least one dose of tirzepatide and had evaluable PK data.

End point type	Secondary
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End point timeframe:

Predose on weeks 3, 6, 8; 12 and 24 hours post first dose; Within 24 to 96 hours post-dose at week 4; Within 120 to 168 hours post-dose at week 6.

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: No inferential statistics was planned for this end point.

End point values	Cohort 1: 2.5-5 mg Tirzepatide (BW >=50 kg)	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	7	7	
Units: nanogram *hour per milliliter				
arithmetic mean (standard deviation)	105000 (± 33100)	80800 (± 9580)	156000 (± 22500)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Maximum Concentration (Cmax) of Tirzepatide

End point title	PK: Maximum Concentration (Cmax) of Tirzepatide ^[3]
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End point description:

PK: Cmax of tirzepatide

APD: All participants who received at least one dose of tirzepatide and had evaluable PK data.

End point type	Secondary
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End point timeframe:

Predose on weeks 3, 6, 8; 12 and 24 hours post first dose; Within 24 to 96 hours post-dose at week 4; Within 120 to 168 hours post-dose at week 6.

Notes:

[3] - 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: No inferential statistics was planned for this end point.

End point values	Cohort 1: 2.5-5 mg Tirzepatide (BW >=50 kg)	Cohort 2: 1.25-2.5 mg Tirzepatide (BW <50 kg)	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	7	7	
Units: nanograms per milliliter				
arithmetic mean (standard deviation)	884 (± 243)	674 (± 63.8)	1280 (± 194)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline Up To 14 Weeks

Adverse event reporting additional description:

All participants who received at least one dose of study drug. Per protocol, Adverse Event analysis was planned as per treatment regimen received.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.1
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Reporting groups

Reporting group title	Cohort 1: Placebo (BW \geq 50 kg)
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Reporting group description:

Participants in this cohort had a screening body weight of at least 50 kg, received placebo administered SC QW during Weeks 1 to 8.

Reporting group title	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)
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Reporting group description:

Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received 2.5 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.

Reporting group title	Cohort 2: 1.25-2.5 mg tirzepatide QW (BW <50 kg)
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Reporting group description:

Participants in this cohort had a screening body weight less than 50 kg, received 1.25 mg tirzepatide administered SC QW during Weeks 1 to 4 followed by 2.5 mg tirzepatide during Weeks 5 to 8.

Reporting group title	Cohort 3: Placebo (BW 40 to 60 kg)
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Reporting group description:

Participants in this cohort had a screening body weight between 40 to 60 kg, inclusive, received placebo administered SC QW during Weeks 1 to 8.

Reporting group title	Cohort 1: 2.5-5 mg Tirzepatide (BW \geq 50 kg)
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Reporting group description:

Participants in this cohort had a screening body weight of at least 50 kg, received 2.5 milligrams (mg) tirzepatide administered SC QW during Weeks 1 to 4 followed by 5 mg tirzepatide during Weeks 5 to 8.

Reporting group title	Cohort 2: Placebo (BW <50 kg)
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Reporting group description:

Participants in this cohort had a screening body weight less than 50 kg received placebo administered SC QW during Weeks 1 to 8.

Serious adverse events	Cohort 1: Placebo (BW \geq 50 kg)	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)	Cohort 2: 1.25-2.5 mg tirzepatide QW (BW <50 kg)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Cohort 3: Placebo (BW 40 to 60 kg)	Cohort 1: 2.5-5 mg Tirzepatide (BW	Cohort 2: Placebo (BW <50 kg)
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		>=50 kg)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

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

Non-serious adverse events	Cohort 1: Placebo (BW >=50 kg)	Cohort 3: 2.5-5 mg Tirzepatide (BW 40 to 60 kg)	Cohort 2: 1.25-2.5 mg tirzepatide QW (BW <50 kg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	7 / 7 (100.00%)	6 / 7 (85.71%)
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
injection site erythema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
injection site reaction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
pyrexia			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	4 / 7 (57.14%)	1 / 7 (14.29%)
occurrences (all)	0	9	2
constipation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	3 / 7 (42.86%)	0 / 7 (0.00%)
occurrences (all)	0	7	0
dyspepsia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
eructation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
flatulence			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 2 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
nausea			
alternative dictionary used: MedDRA 25.1			

<p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>5 / 7 (71.43%)</p> <p>2 / 7 (28.57%)</p> <p>occurrences (all)</p> <p>0</p> <p>7</p> <p>2</p>			
<p>vomiting</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>6 / 7 (85.71%)</p> <p>1 / 7 (14.29%)</p> <p>occurrences (all)</p> <p>0</p> <p>11</p> <p>1</p>			
<p>Respiratory, thoracic and mediastinal disorders</p> <p>cough</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0 / 7 (0.00%)</p> <p>1 / 7 (14.29%)</p> <p>occurrences (all)</p> <p>0</p> <p>0</p> <p>1</p> <p>oropharyngeal pain</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>1 / 7 (14.29%)</p> <p>1 / 7 (14.29%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p> <p>1</p>			
<p>Skin and subcutaneous tissue disorders</p> <p>rash</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0 / 7 (0.00%)</p> <p>1 / 7 (14.29%)</p> <p>occurrences (all)</p> <p>0</p> <p>0</p> <p>1</p> <p>solar dermatitis</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>1 / 7 (14.29%)</p> <p>0 / 7 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p> <p>0</p>			
<p>Renal and urinary disorders</p> <p>pollakiuria</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0 / 7 (0.00%)</p> <p>1 / 7 (14.29%)</p> <p>occurrences (all)</p> <p>0</p> <p>0</p> <p>1</p>			
<p>Musculoskeletal and connective tissue disorders</p> <p>myalgia</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0 / 7 (0.00%)</p> <p>1 / 7 (14.29%)</p> <p>occurrences (all)</p> <p>0</p> <p>0</p> <p>1</p> <p>pain in extremity</p>			

alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1
Infections and infestations gastroenteritis alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1
otitis media alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1
pneumonia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0
urinary tract infection alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1	1 / 7 (14.29%) 1
hypoglycaemia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0

Non-serious adverse events	Cohort 3: Placebo (BW 40 to 60 kg)	Cohort 1: 2.5-5 mg Tirzepatide (BW ≥50 kg)	Cohort 2: Placebo (BW <50 kg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	5 / 6 (83.33%)	0 / 2 (0.00%)
Nervous system disorders			

dizziness alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
headache alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
General disorders and administration site conditions			
fatigue alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
injection site erythema alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
injection site reaction alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
pyrexia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal disorders			
abdominal pain alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 5	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
constipation alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	2 / 6 (33.33%) 2	0 / 2 (0.00%) 0
diarrhoea			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
dyspepsia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
eructation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
vomiting			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Skin and subcutaneous tissue disorders rash alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) solar dermatitis alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0
Renal and urinary disorders pollakiuria alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Musculoskeletal and connective tissue disorders myalgia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) pain in extremity alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0
Infections and infestations gastroenteritis alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) otitis media alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) pneumonia	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0

alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
urinary tract infection alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 6 (50.00%) 3	0 / 2 (0.00%) 0
hypoglycaemia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 November 2023	- Updated schema to reflect body weight range for Cohort 3; - Modified rationale and text to include body weight range in Cohort 3.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported