



Clinical trial results:

A Study to Evaluate the Pharmacokinetics and Glucodynamics of LY900014 Compared to Humalog in Children, Adolescents, and Adults with Type 1 Diabetes Mellitus

Summary

EudraCT number	2017-003220-78
Trial protocol	DE
Global end of trial date	14 November 2019

Results information

Result version number	v1 (current)
This version publication date	21 May 2020
First version publication date	21 May 2020

Trial information

Trial identification

Sponsor protocol code	I8B-MC-ITSA
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03465878
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16695

Notes:

Sponsors

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,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559,

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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 November 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	14 November 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to compare LY900014 with insulin lispro (Humalog) in participants with type 1 diabetes mellitus.

There are 2 parts to this study. Part A is investigating how the body processes LY900014 and the effect of LY900014 on blood sugar levels compared to insulin lispro (Humalog) when study treatment is given by subcutaneous injection. Part B of the study is investigating how the body processes LY900014 and the effect of LY900014 on blood sugar levels compared to insulin lispro (Humalog) when study treatment is given by continuous subcutaneous insulin infusion (CSII) pump.

Screening is required within 28 days prior to the start of the study. For each participant, the study will last about 40 days in each part.

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	26 March 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	Canada: 53
Country: Number of subjects enrolled	Germany: 28
Worldwide total number of subjects	81
EEA total number of subjects	28

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)	25
Adolescents (12-17 years)	27
Adults (18-64 years)	29
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants who completed Part A but discontinued before the beginning of Part B were replaced by newly enrolled participants in Part B.

Pre-assignment

Screening details:

No Text Available

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1-Part A

Arm description:

Participants received either single 0.2 U/kg of body weight subcutaneous (SC) bolus injection of 100 U/mL LY900014 or Humalog.

Period 1: LY900014

Period 2: Humalog

Arm type	Experimental
Investigational medicinal product name	LY900014
Investigational medicinal product code	
Other name	Ultra-Rapid Lispro
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014.

Investigational medicinal product name	Humalog
Investigational medicinal product code	
Other name	Insulin Lispro; LY275585
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single 0.2 U/kg of body weight SC bolus injection of 100 U/mL Humalog.

Arm title	Sequence 2-Part A
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Arm description:

Participants received either single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014 or Humalog.

Period 1: Humalog

Period 2: LY900014

Arm type	Active comparator
Investigational medicinal product name	LY900014
Investigational medicinal product code	
Other name	Ultra-Rapid Lispro
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details: Single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014.	
Investigational medicinal product name	Humalog
Investigational medicinal product code	
Other name	Insulin Lispro; LY275585
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: Single 0.2 U/kg of body weight SC bolus injection of 100 U/mL Humalog.	
Arm title	Sequence 1-Part B
Arm description: Participants received either single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 or Humalog delivered using the CSII pump. Period 1: LY900014 Period 2: Humalog	
Arm type	Experimental
Investigational medicinal product name	LY900014
Investigational medicinal product code	
Other name	Ultra-Rapid Lispro
Pharmaceutical forms	Infusion
Routes of administration	Subcutaneous use
Dosage and administration details: Single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 delivered using the CSII pump.	
Investigational medicinal product name	Humalog
Investigational medicinal product code	
Other name	Insulin Lispro; LY275585
Pharmaceutical forms	Infusion
Routes of administration	Subcutaneous use
Dosage and administration details: Single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL Humalog delivered using the CSII pump.	
Arm title	Sequence 2-Part B
Arm description: Participants received either single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 or Humalog with delivered using the CSII pump. Period 1: Humalog Period 2: LY900014	
Arm type	Active comparator
Investigational medicinal product name	LY900014
Investigational medicinal product code	
Other name	Ultra-Rapid Lispro
Pharmaceutical forms	Infusion
Routes of administration	Subcutaneous use
Dosage and administration details: Single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 delivered using the CSII pump.	
Investigational medicinal product name	Humalog
Investigational medicinal product code	
Other name	Insulin Lispro; LY275585
Pharmaceutical forms	Infusion
Routes of administration	Subcutaneous use
Dosage and administration details: Single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL Humalog delivered using the CSII pump.	

Number of subjects in period 1	Sequence 1-Part A	Sequence 2-Part A	Sequence 1-Part B
Started	21	21	20
Received at least 1 dose of study drug	21	21	20
Participants Moved From Part A to Part B	0 ^[1]	0 ^[2]	15 ^[3]
Children (2-11 Years)	7 ^[4]	6 ^[5]	6 ^[6]
Adolescents (12-17 Years)	7 ^[7]	7 ^[8]	7 ^[9]
Adults (18-64 Years)	7 ^[10]	8 ^[11]	7 ^[12]
Completed	21	20	20
Not completed	0	1	0
Consent withdrawn by subject	-	1	-
Physician decision	-	-	-

Number of subjects in period 1	Sequence 2-Part B
Started	19
Received at least 1 dose of study drug	17
Participants Moved From Part A to Part B	10 ^[13]
Children (2-11 Years)	6 ^[14]
Adolescents (12-17 Years)	6 ^[15]
Adults (18-64 Years)	7 ^[16]
Completed	17
Not completed	2
Consent withdrawn by subject	1
Physician decision	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that

completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[15] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[16] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

Period 2

Period 2 title	Period 2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
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Arm title	Sequence 1-Part A
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Arm description:

Participants received either single 0.2 U/kg of body weight subcutaneous (SC) bolus injection of 100 U/mL LY900014 or Humalog.

Period 1: LY900014

Period 2: Humalog

Arm type	Experimental
Investigational medicinal product name	LY900014
Investigational medicinal product code	
Other name	Ultra-Rapid Lispro
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single, subcutaneous (SC) dose of LY900014 administered via injection, in one of two study periods.

Investigational medicinal product name	Humalog
Investigational medicinal product code	
Other name	Insulin Lispro; LY275585
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single, SC dose of insulin lispro (Humalog) administered via injection, in one of two study periods.

Arm title	Sequence 2-Part A
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Arm description:

Participants received either single 0.2 U/kg of body weight subcutaneous (SC) bolus injection of 100 U/mL LY900014 or Humalog.

Period 1: Humalog

Period 2: LY900014

Arm type	Experimental
Investigational medicinal product name	LY900014
Investigational medicinal product code	
Other name	Ultra-Rapid Lispro
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single, subcutaneous (SC) dose of LY900014 administered via injection, in one of two study periods.

Investigational medicinal product name	Humalog
Investigational medicinal product code	
Other name	Insulin Lispro; LY275585
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single, SC dose of insulin lispro (Humalog) administered via injection, in one of two study periods.

Arm title	Sequence 1-Part B
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Arm description:

Participants received either single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 or Humalog delivered using the CSII pump.

Period 1: LY900014

Period 2: Humalog

Arm type	Experimental
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Investigational medicinal product name	LY900014
Investigational medicinal product code	
Other name	Ultra-Rapid Lispro
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single, subcutaneous (SC) dose of LY900014 administered via injection, in one of two study periods.

Investigational medicinal product name	Humalog
Investigational medicinal product code	
Other name	Insulin Lispro; LY275585
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single, SC dose of insulin lispro (Humalog) administered via injection, in one of two study periods.

Arm title	Sequence 2-Part B
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Arm description:

Participants received either single 0.2 U/kg of body weight subcutaneous (SC) bolus infusion of 100 U/mL LY900014 or Humalog with delivered using the CSII pump.

Period 1: Humalog
Period 2: LY900014

Arm type	Experimental
Investigational medicinal product name	LY900014
Investigational medicinal product code	
Other name	Ultra-Rapid Lispro
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single, subcutaneous (SC) dose of LY900014 administered via injection, in one of two study periods.

Investigational medicinal product name	Humalog
Investigational medicinal product code	
Other name	Insulin Lispro; LY275585
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Single, SC dose of insulin lispro (Humalog) administered via injection, in one of two study periods.

Number of subjects in period 2	Sequence 1-Part A	Sequence 2-Part A	Sequence 1-Part B
Started	21	20	20
Children (2-11 Years)	7 ^[17]	6 ^[18]	6 ^[19]
Adolescents (12-17 Years)	7 ^[20]	7 ^[21]	7 ^[22]
Adults (18-64 Years)	7 ^[23]	7 ^[24]	7 ^[25]
Completed	21	20	20

Number of subjects in period 2	Sequence 2-Part B
Started	17
Children (2-11 Years)	6 ^[26]

Adolescents (12-17 Years)	6 [27]
Adults (18-64 Years)	5 [28]
Completed	17

Notes:

[17] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[18] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[19] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[20] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[21] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[22] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[23] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[24] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences.

[25] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[26] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[27] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

[28] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestones were added to show Age group differences and for the participants who moved from Part A to Part B.

Baseline characteristics

Reporting groups

Reporting group title	Period 1
Reporting group description: -	

Reporting group values	Period 1	Total	
Number of subjects	81	81	
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)	25	25	
Adolescents (12-17 years)	27	27	
Adults (18-64 years)	29	29	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	41	41	
Male	40	40	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	2	
Not Hispanic or Latino	79	79	
Unknown or Not Reported	0	0	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	4	4	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	1	1	
White	71	71	
More than one race	5	5	
Unknown or Not Reported	0	0	
Region of Enrollment			
Units: Subjects			
Canada	53	53	
Germany	28	28	

Subject analysis sets

Subject analysis set title	Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014 or Humalog.

Subject analysis set title	Part B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight subcutaneous (SC) bolus infusion of either 100 U/mL LY900014 or Humalog delivered using the CSII pump.

Subject analysis set title	Children-LY900014-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014.

Subject analysis set title	Children-Humalog-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL Humalog.

Subject analysis set title	Adolescents-LY900014-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014.

Subject analysis set title	Adolescents-Humalog-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL Humalog.

Subject analysis set title	Adults-LY900014-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100U/mL LY900014.

Subject analysis set title	Adults-Humalog-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL Humalog.

Subject analysis set title	Children-LY900014-Part B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 delivered using the CSII pump.

Subject analysis set title	Children-Humalog-Part B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL Humalog delivered using the CSII pump.

Subject analysis set title	Adolescents-LY900014-Part B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 delivered using the CSII pump.

Subject analysis set title	Adolescents-Humalog-Part B
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL Humalog delivered using the CSII pump.

Subject analysis set title	Adults-LY900014-Part B
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 delivered using the CSII pump.

Subject analysis set title	Adults-Humalog-Part B
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL Humalog delivered using the CSII pump.

Reporting group values	Part A	Part B	Children-LY900014-Part A
Number of subjects	42	14	13
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported	0		
Region of Enrollment Units: Subjects			

Canada			
Germany			

Reporting group values	Children-Humalog-Part A	Adolescents-LY900014-Part A	Adolescents-Humalog-Part A
Number of subjects	13	14	14
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Region of Enrollment Units: Subjects			
Canada Germany			

Reporting group values	Adults-LY900014-Part A	Adults-Humalog-Part A	Children-LY900014-Part B
Number of subjects	14	14	11
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days)			

Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Region of Enrollment Units: Subjects			
Canada Germany			

Reporting group values	Children-Humalog-Part B	Adolescents-LY900014-Part B	Adolescents-Humalog-Part B
Number of subjects	11	13	13
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender categorical Units: Subjects			
Female Male			

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Region of Enrollment Units: Subjects			
Canada Germany			

Reporting group values	Adults-LY900014-Part B	Adults-Humalog-Part B	
Number of subjects	12	12	
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender categorical Units: Subjects			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White			

More than one race Unknown or Not Reported			
Region of Enrollment Units: Subjects			
Canada Germany			

End points

End points reporting groups

Reporting group title	Sequence 1-Part A
Reporting group description: Participants received either single 0.2 U/kg of body weight subcutaneous (SC) bolus injection of 100 U/mL LY900014 or Humalog. Period 1: LY900014 Period 2: Humalog	
Reporting group title	Sequence 2-Part A
Reporting group description: Participants received either single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014 or Humalog. Period 1: Humalog Period 2: LY900014	
Reporting group title	Sequence 1-Part B
Reporting group description: Participants received either single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 or Humalog delivered using the CSII pump. Period 1: LY900014 Period 2: Humalog	
Reporting group title	Sequence 2-Part B
Reporting group description: Participants received either single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 or Humalog with delivered using the CSII pump. Period 1: Humalog Period 2: LY900014	
Reporting group title	Sequence 1-Part A
Reporting group description: Participants received either single 0.2 U/kg of body weight subcutaneous (SC) bolus injection of 100 U/mL LY900014 or Humalog. Period 1: LY900014 Period 2: Humalog	
Reporting group title	Sequence 2-Part A
Reporting group description: Participants received either single 0.2 U/kg of body weight subcutaneous (SC) bolus injection of 100 U/mL LY900014 or Humalog. Period 1: Humalog Period 2: LY900014	
Reporting group title	Sequence 1-Part B
Reporting group description: Participants received either single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 or Humalog delivered using the CSII pump. Period 1: LY900014 Period 2: Humalog	
Reporting group title	Sequence 2-Part B
Reporting group description: Participants received either single 0.2 U/kg of body weight subcutaneous (SC) bolus infusion of 100 U/mL LY900014 or Humalog with delivered using the CSII pump. Period 1: Humalog Period 2: LY900014	
Subject analysis set title	Part A
Subject analysis set type	Per protocol
Subject analysis set description: Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014 or Humalog.	
Subject analysis set title	Part B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight subcutaneous (SC) bolus infusion of either 100 U/mL LY900014 or Humalog delivered using the CSII pump.

Subject analysis set title	Children-LY900014-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014.

Subject analysis set title	Children-Humalog-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL Humalog.

Subject analysis set title	Adolescents-LY900014-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL LY900014.

Subject analysis set title	Adolescents-Humalog-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL Humalog.

Subject analysis set title	Adults-LY900014-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100U/mL LY900014.

Subject analysis set title	Adults-Humalog-Part A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus injection of 100 U/mL Humalog.

Subject analysis set title	Children-LY900014-Part B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 delivered using the CSII pump.

Subject analysis set title	Children-Humalog-Part B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL Humalog delivered using the CSII pump.

Subject analysis set title	Adolescents-LY900014-Part B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 delivered using the CSII pump.

Subject analysis set title	Adolescents-Humalog-Part B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL Humalog delivered using the CSII pump.

Subject analysis set title	Adults-LY900014-Part B
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL LY900014 delivered using the CSII pump.

Subject analysis set title	Adults-Humalog-Part B
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received single 0.2 U/kg of body weight SC bolus infusion of 100 U/mL Humalog delivered using the CSII pump.

Primary: Pharmacokinetics (PK): Insulin Lispro Area Under the Concentration Curve (AUC) following Each Treatment Arm for Each Study Part

End point title	Pharmacokinetics (PK): Insulin Lispro Area Under the Concentration Curve (AUC) following Each Treatment Arm for Each Study Part
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End point description:

Pharmacokinetics (PK): Insulin Lispro Area Under the Concentration Curve (AUC(0 -7h)) following Each Treatment Arm for Each Study Part.

Analysis Population Description: All randomized participants who received at least one dose of study drug and had evaluable PK data.

End point type	Primary
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End point timeframe:

Predose, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 60, 70, 90, 120, 150, 180, 240, 300, 360, and 420 minutes postdose

End point values	Children-LY900014-Part A	Children-Humalog-Part A	Adolescents-LY900014-Part A	Adolescents-Humalog-Part A
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: picomols * hour per Liter				
geometric mean (geometric coefficient of variation)	755 (± 15)	754 (± 17)	962 (± 17)	908 (± 21)

End point values	Adults-LY900014-Part A	Adults-Humalog-Part A	Children-LY900014-Part B	Children-Humalog-Part B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	14	11	11
Units: picomols * hour per Liter				
geometric mean (geometric coefficient of variation)	987 (± 20)	975 (± 21)	743 (± 17)	714 (± 17)

End point values	Adolescents-LY900014-Part B	Adolescents-Humalog-Part B	Adults-LY900014-Part B	Adults-Humalog-Part B
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Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	11	12
Units: picomols * hour per Liter				
geometric mean (geometric coefficient of variation)	842 (± 20)	866 (± 16)	1100 (± 35)	1070 (± 35)

Statistical analyses

Statistical analysis title	AUC(0 -7h)
Comparison groups	Children-LY900014-Part A v Children-Humalog-Part A
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9813
Method	Mixed models analysis
Parameter estimate	Ratio of geometric least squares means
Point estimate	0.999
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.918
upper limit	1.09

Statistical analysis title	AUC(0 -7h)
Comparison groups	Adolescents-LY900014-Part A v Adolescents-Humalog-Part A
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1638
Method	Mixed models analysis
Parameter estimate	Ratio of geometric least squares means
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.976
upper limit	1.15

Statistical analysis title	AUC(0 -7h)
Comparison groups	Adults-LY900014-Part A v Adults-Humalog-Part A

Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7623
Method	Mixed models analysis
Parameter estimate	Ratio of geometric least squares means
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.933
upper limit	1.1

Statistical analysis title	AUC(0 -7h)
Comparison groups	Children-LY900014-Part B v Children-Humalog-Part B
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2952
Method	Mixed models analysis
Parameter estimate	Ratio of geometric least squares means
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.962
upper limit	1.13

Statistical analysis title	AUC(0 -7h)
Comparison groups	Adolescents-LY900014-Part B v Adolescents-Humalog-Part B
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4052
Method	Mixed models analysis
Parameter estimate	Ratio of geometric least squares means
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.901
upper limit	1.04

Statistical analysis title	AUC(0 -7h)
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Comparison groups	Adults-LY900014-Part B v Adults-Humalog-Part B
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5314
Method	Mixed models analysis
Parameter estimate	Ratio of geometric least squares means
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.948
upper limit	1.11

Secondary: Glucodynamics (GD): Area Under the Baseline Subtracted Glucose Concentration Versus Time Curve Following Each Treatment Arm for Each Study Part

End point title	Glucodynamics (GD): Area Under the Baseline Subtracted Glucose Concentration Versus Time Curve Following Each Treatment Arm for Each Study Part
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End point description:

Glucodynamics (GD): Area Under the Baseline Subtracted Glucose Concentration Versus Time Curve (BGΔAUC(0-5h)) Following Each Treatment Arm for Each Study Part.

Analysis Population Description: All randomized participants who received at least one dose of study drug and had evaluable Glucodynamics data.

End point type	Secondary
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End point timeframe:

-30, -15, 0 (predose), 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 135, 150, 165, 180, 195, 210, 225, 240 and 300 minutes postdose

End point values	Children-LY900014-Part A	Children-Humalog-Part A	Adolescents-LY900014-Part A	Adolescents-Humalog-Part A
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	12	12	13	13
Units: milligrams * hour per deciliter				
arithmetic mean (standard deviation)	384 (± 335)	492 (± 270)	577 (± 247)	651 (± 238)

End point values	Adults-LY900014-Part A	Adults-Humalog-Part A	Children-LY900014-Part B	Children-Humalog-Part B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	14	10	10
Units: milligrams * hour per deciliter				
arithmetic mean (standard deviation)	372 (± 179)	351 (± 240)	602 (± 221)	582 (± 254)

End point values	Adolescents- LY900014-Part B	Adolescents- Humalog-Part B	Adults- LY900014-Part B	Adults- Humalog-Part B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	12	12
Units: milligrams * hour per deciliter				
arithmetic mean (standard deviation)	614 (± 160)	614 (± 163)	343 (± 194)	401 (± 235)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

I8B-MC-ITSA

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.1
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Reporting groups

Reporting group title	Children-LY900014-Part A
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Reporting group description: -

Reporting group title	Children-Humalog-Part A
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Reporting group description: -

Reporting group title	Adolescents-LY900014-Part A
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Reporting group description: -

Reporting group title	Adolescents-Humalog-Part A
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Reporting group description: -

Reporting group title	Adults-LY900014-Part A
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Reporting group description: -

Reporting group title	Adults-Humalog-Part A
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Reporting group description: -

Reporting group title	Children-LY900014-Part B
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Reporting group description: -

Reporting group title	Children-Humalog-Part B
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Reporting group description: -

Reporting group title	Adolescents-LY900014-Part B
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Reporting group description: -

Reporting group title	Adolescents-Humalog-Part B
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Reporting group description: -

Reporting group title	Adults-LY900014-Part B
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Reporting group description: -

Reporting group title	Adults-Humalog-Part B
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Reporting group description: -

Serious adverse events	Children-LY900014-Part A	Children-Humalog-Part A	Adolescents-LY900014-Part A
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
injury			
alternative dictionary used:			

MedDRA 21.1			
subjects affected / exposed	0 / 13 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adolescents-Humalog-Part A	Adults-LY900014-Part A	Adults-Humalog-Part A
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (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	Children-LY900014-Part B	Children-Humalog-Part B	Adolescents-LY900014-Part B
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 13 (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	Adolescents-Humalog-Part B	Adults-LY900014-Part B	Adults-Humalog-Part B
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			

injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

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

Non-serious adverse events	Children-LY900014- Part A	Children-Humalog- Part A	Adolescents- LY900014-Part A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 13 (30.77%)	4 / 13 (30.77%)	6 / 14 (42.86%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
lipoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 13 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
feeling hot			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 13 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site discomfort			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 13 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 13 (15.38%)	0 / 13 (0.00%)	2 / 14 (14.29%)
occurrences (all)	2	0	2
injection site pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 13 (7.69%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
injection site pruritus			

<p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>
<p>Immune system disorders</p> <p>seasonal allergy</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 14 (7.14%)</p> <p>1</p>
<p>Reproductive system and breast disorders</p> <p>dysmenorrhoea</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ovarian cyst ruptured</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p> <p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 13 (0.00%)</p> <p>0</p> <p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p> <p>0 / 14 (0.00%)</p> <p>0</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>epistaxis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>
<p>Injury, poisoning and procedural complications</p> <p>procedural pain</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>
<p>Nervous system disorders</p> <p>dizziness</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>headache</p> <p>alternative dictionary used: MedDRA 21.1</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	0 / 14 (0.00%) 0
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	0 / 14 (0.00%) 0
nausea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 13 (0.00%) 0	1 / 14 (7.14%) 1
vomiting alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	0 / 14 (0.00%) 0
Skin and subcutaneous tissue disorders lipohypertrophy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 13 (7.69%) 1	1 / 14 (7.14%) 1
Renal and urinary disorders leukocyturia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 13 (7.69%) 1	0 / 14 (0.00%) 0
Endocrine disorders hypothyroidism alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	1 / 14 (7.14%) 1
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	1 / 14 (7.14%) 1
Infections and infestations			

acne pustular alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	1 / 14 (7.14%) 1
cystitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	0 / 14 (0.00%) 0
ear infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	0 / 14 (0.00%) 0
gastroenteritis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	0 / 14 (0.00%) 0
groin abscess alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	1 / 14 (7.14%) 1
nasopharyngitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	2 / 13 (15.38%) 2	1 / 14 (7.14%) 1
upper respiratory tract infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 13 (0.00%) 0	0 / 14 (0.00%) 0
Metabolism and nutrition disorders hyperglycaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 13 (7.69%) 1	0 / 14 (0.00%) 0

Non-serious adverse events	Adolescents- Humalog-Part A	Adults-LY900014- Part A	Adults-Humalog-Part A
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Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 14 (21.43%)	2 / 14 (14.29%)	2 / 15 (13.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) lipoma alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
General disorders and administration site conditions feeling hot alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
injection site discomfort alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
injection site erythema alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	1 / 14 (7.14%) 1	0 / 15 (0.00%) 0
injection site pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
injection site pruritus alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Immune system disorders seasonal allergy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Reproductive system and breast disorders			

dysmenorrhoea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
ovarian cyst ruptured alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	1 / 15 (6.67%) 1
Respiratory, thoracic and mediastinal disorders epistaxis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Injury, poisoning and procedural complications procedural pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 14 (0.00%) 0	0 / 15 (0.00%) 0
Nervous system disorders dizziness alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) headache alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0 0 / 14 (0.00%) 0	0 / 14 (0.00%) 0 0 / 14 (0.00%) 0	0 / 15 (0.00%) 0 1 / 15 (6.67%) 1
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) nausea alternative dictionary used: MedDRA 21.1	0 / 14 (0.00%) 0 0 / 14 (0.00%) 0	0 / 14 (0.00%) 0 0 / 14 (0.00%) 0	0 / 15 (0.00%) 0 0 / 15 (0.00%) 0

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>vomiting</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 14 (0.00%)</p> <p>0</p> <p>1 / 14 (7.14%)</p> <p>1</p>	<p>1 / 14 (7.14%)</p> <p>1</p> <p>1 / 14 (7.14%)</p> <p>1</p>	<p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p>
<p>Skin and subcutaneous tissue disorders</p> <p>lipohypertrophy</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 14 (7.14%)</p> <p>1</p>	<p>0 / 14 (0.00%)</p> <p>0</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>Renal and urinary disorders</p> <p>leukocyturia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 14 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>Endocrine disorders</p> <p>hypothyroidism</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 14 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 14 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>	<p>0 / 15 (0.00%)</p> <p>0</p>
<p>Infections and infestations</p> <p>acne pustular</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>cystitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ear infection</p>	<p>0 / 14 (0.00%)</p> <p>0</p> <p>0 / 14 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p> <p>0 / 14 (0.00%)</p> <p>0</p>	<p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p>

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
groin abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
hyperglycaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Children-LY900014- Part B	Children-Humalog- Part B	Adolescents- LY900014-Part B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 12 (50.00%)	4 / 12 (33.33%)	3 / 13 (23.08%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
lipoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

feeling hot alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
injection site discomfort alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 13 (7.69%) 1
injection site erythema alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
injection site pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	1 / 13 (7.69%) 1
injection site pruritus alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Immune system disorders seasonal allergy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Reproductive system and breast disorders dysmenorrhoea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
ovarian cyst ruptured alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Respiratory, thoracic and mediastinal			

disorders epistaxis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
Injury, poisoning and procedural complications procedural pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Nervous system disorders dizziness alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) headache alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0 0 / 12 (0.00%) 0	1 / 12 (8.33%) 1 0 / 12 (0.00%) 0	0 / 13 (0.00%) 0 0 / 13 (0.00%) 0
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) nausea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) vomiting alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0	1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0	0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0
Skin and subcutaneous tissue disorders lipohypertrophy alternative dictionary used: MedDRA 21.1			

subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	1 / 13 (7.69%) 1
Renal and urinary disorders leukocyturia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Endocrine disorders hypothyroidism alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
Infections and infestations acne pustular alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
cystitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
ear infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	0 / 13 (0.00%) 0
gastroenteritis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 13 (0.00%) 0
groin abscess			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
hyperglycaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Adolescents- Humalog-Part B	Adults-LY900014- Part B	Adults-Humalog-Part B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 13 (7.69%)	3 / 12 (25.00%)	2 / 12 (16.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
lipoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
feeling hot			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
injection site discomfort			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
injection site erythema			

<p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>
<p>injection site pain</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>	<p>1 / 12 (8.33%)</p> <p>1</p>
<p>injection site pruritus</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>
<p>Immune system disorders</p> <p>seasonal allergy</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>
<p>Reproductive system and breast disorders</p> <p>dysmenorrhoea</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ovarian cyst ruptured</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p> <p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p> <p>0 / 12 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>epistaxis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>
<p>Injury, poisoning and procedural complications</p> <p>procedural pain</p> <p>alternative dictionary used: MedDRA 21.1</p>			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Nervous system disorders dizziness alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
headache alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
nausea alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
vomiting alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Skin and subcutaneous tissue disorders lipohypertrophy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Renal and urinary disorders leukocyturia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Endocrine disorders			

hypothyroidism alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Infections and infestations acne pustular alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
cystitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
ear infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
gastroenteritis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
groin abscess alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
nasopharyngitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
upper respiratory tract infection			

alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Metabolism and nutrition disorders hyperglycaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 March 2018	Protocol (b): Total daily insulin dose was updated in inclusion criteria.
17 April 2018	Protocol (c): Inpatient Procedures for Part A and B was updated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported