Clinical trial results:
To evaluate if 24 weeks treatment with Lixisenatide, reduces arterial stiffness as measured by aortic pulse wave velocity (Ao-PWV) in T2DM patients with diabetic nephropathy (DN)

Summary

EudraCT number	2016-001758-17
Trial protocol	GB
Global end of trial date	15 September 2023

Results information

Result version number	v1 (current)
This version publication date	08 May 2026
First version publication date	08 May 2026
Summary attachment (see zip file)	LAST CSR v3.0 Final Signed (Clinical Study Report v3.0 final signed May2025.pdf)

Trial information

Trial identification

Sponsor protocol code	LAST

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	King's College London
Sponsor organisation address	The Strand, London, United Kingdom, WC2R 2LS
Public contact	Janaka Karalliedde, King's College London, 44 02078484464, j.karalliedde@kcl.ac.uk
Scientific contact	Janaka Karalliedde, King's College London, 44 02078484464, j.karalliedde@kcl.ac.uk
Sponsor organisation name	Guy's and St Thomas NHS Foundation Trust
Sponsor organisation address	Great Maze Pond, London, United Kingdom, SE1 9RT
Public contact	Janaka Karalliedde, Guy's and St Thomas' NHS Foundation Trust, 44 02078484464, j.karalliedde@kcl.ac.uk
Scientific contact	Janaka Karalliedde, Guy's and St Thomas' NHS Foundation Trust, 44 02078484464, j.karalliedde@kcl.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 September 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 May 2023
Global end of trial reached?	Yes
Global end of trial date	15 September 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate if treatment with Lixisenatide for 24 weeks reduces Ao-PWV in T2DM with DN.

Protection of trial subjects:

Participants have the right to withdraw from the study at any time for any reason. The investigator also has the right to withdraw patients from the study drug in the event of inter- current illness, AEs, SAE's, SUSAR's, protocol violations, administrative reasons or other reasons.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 January 2017
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 Kingdom: 101
Worldwide total number of subjects	101
EEA total number of subjects	101

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	77
From 65 to 84 years	24

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	143[1]
Number of subjects completed	101

Pre-assignment subject non-completion reasons

Reason: Number of subjects	N/A: 42

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: We do not count screening participants as enrolled

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Active

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lixisenatide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

10mcg od increasing to 20mcg od within 14 days from the start of treatment

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

dosage of 10mcg od increasing to 20mcg od within 14 days from the start of treatment

Number of subjects in period 1	Active	Placebo
Started	51	50
Completed	47	43
Not completed	4	7
N/A	4	7

Baseline characteristics

Reporting groups	
Reporting group title	Active
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Active	Placebo	Total
Number of subjects	51	50	101
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)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	61.5	67.2	
standard deviation	± 10.2	± 11.9	-
Gender categorical Units: Subjects			
Female	19	16	35
Male	32	34	66

End points

End points reporting groups

Reporting group title	Active
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Aortic Pulse Wave Velocity

End point title	Aortic Pulse Wave Velocity[1]
End point description:	
End point type	Primary
End point timeframe:	
Following 24-week treatment	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Please see uploaded report

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	50		
Units: m/s				
arithmetic mean (confidence interval 95%)	9.65 (9.17 to 10.13)	9.96 (9.45 to 10.46)		

Statistical analyses

No statistical analyses for this end point

Secondary: Albuminuria excretion rate

End point title	Albuminuria excretion rate
End point description:	
End point type	Secondary
End point timeframe:	
Following 24-week treatment	

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	50		
Units: mcg/min				
arithmetic mean (confidence interval 95%)	449.94 (253.54 to 646.34)	208.26 (6.97 to 409.56)		

Statistical analyses

No statistical analyses for this end point

Secondary: Central systolic blood pressure

End point title	Central systolic blood pressure

End point description:

End point type	Secondary

End point timeframe:

Following 24-week treatment

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	50		
Units: mm/Hg				
arithmetic mean (confidence interval 95%)	121.95 (117.97 to 125.93)	208.26 (6.97 to 409.56)		

Statistical analyses

No statistical analyses for this end point

Secondary: Central diastolic blood pressure

End point title	Central diastolic blood pressure

End point description:

End point type	Secondary

End point timeframe:

Following 24-week treatment

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	50		
Units: mm/Hg				
arithmetic mean (confidence interval 95%)	78.83 (76.83 to 80.83)	78.06 (75.97 to 80.15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Seated brachial systolic blood pressure

End point title	Seated brachial systolic blood pressure

End point description:

End point type	Secondary

End point timeframe:

Following 24-week treatment

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	50		
Units: mm/Hg				
arithmetic mean (confidence interval 95%)	136.57 (132.28 to 140.86)	133.45 (128.97 to 137.94)		

Statistical analyses

No statistical analyses for this end point

Secondary: Seated brachial diastolic blood pressure

End point title	Seated brachial diastolic blood pressure

End point description:

End point type	Secondary

End point timeframe:

Following 24-week treatment

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	50		
Units: mm/Hg				
arithmetic mean (confidence interval 95%)	78.46 (76.48 to 80.43)	77.43 (75.37 to 79.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Weight

End point title	Weight

End point description:

End point type	Secondary

End point timeframe:

Following 24-week treatment

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	50		
Units: Kg				
arithmetic mean (confidence interval 95%)	100.58 (98.63 to 102.52)	100.58 (98.54 to 102.62)		

Statistical analyses

No statistical analyses for this end point

Secondary: eGFR/1.73m2

End point title	eGFR/1.73m2

End point description:

End point type	Secondary

End point timeframe:

Following 24-week treatment

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	50		
Units: mL/min				
arithmetic mean (confidence interval 95%)	67.83 (65.4 to 70.27)	66.11 (63.56 to 68.66)		

Statistical analyses

No statistical analyses for this end point

Secondary: HbA1c log transformed

End point title	HbA1c log transformed

End point description:

End point type	Secondary

End point timeframe:

Following 24-week treatment

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	50		
Units: %				
arithmetic mean (confidence interval 95%)	8.94 (8.58 to 9.30)	9.58 (9.12 to 9.97)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 24-weeks following treatment	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.1
Reporting groups	
Reporting group title	Active
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Active	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	0 / 23 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Active	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 21 (100.00%)	23 / 23 (100.00%)	
Vascular disorders			
Other cardiovascular disorders			
subjects affected / exposed	2 / 21 (9.52%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Immune system disorders			
Immunological			
subjects affected / exposed	0 / 21 (0.00%)	2 / 23 (8.70%)	
occurrences (all)	0	2	
Reproductive system and breast disorders			
Genitourinary/Renal			

subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	6 / 23 (26.09%) 6	
Respiratory, thoracic and mediastinal disorders Respiratory/Virus/Flu/Chest infection/Lower respiratory tract infection subjects affected / exposed occurrences (all)	 5 / 21 (23.81%) 7	 7 / 23 (30.43%) 7	
Injury, poisoning and procedural complications Forehead wound subjects affected / exposed occurrences (all)	 1 / 21 (4.76%) 1	 0 / 23 (0.00%) 0	
Cardiac disorders Other cardiovascular disorders subjects affected / exposed occurrences (all)	 2 / 21 (9.52%) 3	 1 / 23 (4.35%) 2	
Nervous system disorders Neurological/Dizziness/Memory loss subjects affected / exposed occurrences (all)	 3 / 21 (14.29%) 0	 0 / 23 (0.00%) 0	
Blood and lymphatic system disorders Hematological subjects affected / exposed occurrences (all)	 0 / 21 (0.00%) 0	 2 / 23 (8.70%) 3	
Eye disorders Eyes, ear, nose, throat subjects affected / exposed occurrences (all)	 1 / 21 (4.76%) 1	 0 / 23 (0.00%) 0	
Gastrointestinal disorders Gastrointestinal/ Tooth subjects affected / exposed occurrences (all)	 4 / 21 (19.05%) 6	 7 / 23 (30.43%) 5	
Skin and subcutaneous tissue disorders Dermatological subjects affected / exposed occurrences (all)	 3 / 21 (14.29%) 4	 4 / 23 (17.39%) 4	
Musculoskeletal and connective tissue disorders			

Musculoskeletal subjects affected / exposed occurrences (all)	8 / 21 (38.10%) 6	2 / 23 (8.70%) 5	
Metabolism and nutrition disorders Endocrine subjects affected / exposed occurrences (all)	6 / 21 (28.57%) 5	4 / 23 (17.39%) 6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 January 2018	Protocol V5.0 30May2017, Invitation letter: Version 3.0 Jun2017 (PIC sites)
19 January 2018	Protocol V6.0 20 November 2017, SmPC: Lixisenatide 10 micrograms solution for injection 18Sep 2017, SmPC: Lixisenatide 20 micrograms solution for injection 18Sep 2017

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported