Clinical trial results:
A multicentre, randomised controlled Trial of Exenatide versus standard care in Acute Ischemic Stroke (TEXAIS)

Summary

EudraCT number	2018-004325-88
Trial protocol	FI
Global end of trial date	02 October 2021

Results information

Result version number	v1 (current)
This version publication date	18 May 2024
First version publication date	18 May 2024

Trial information

Trial identification

Sponsor protocol code	NTA1127

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03287076
WHO universal trial number (UTN)	-
Other trial identifiers	Australian New Zealand Clinical Trials Registry: ACTRN12617000409370

Notes:

Sponsors

Sponsor organisation name	Monash University
Sponsor organisation address	26 Sports Walk, Clayton Campus, Wellington Road, Clayton, Australia, 3800
Public contact	Maddalena Borromeo, Neuroscience Trials Australia, Maddalena.borromeo@florey.edu.au
Scientific contact	Maddalena Borromeo, Neuroscience Trials Australia, Maddalena.borromeo@florey.edu.au

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	27 November 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 October 2021
Global end of trial reached?	Yes
Global end of trial date	02 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare neurological impairment (NIHSS) at 7 days in treated and untreated patients.

Protection of trial subjects:

Informed consent

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 85
Country: Number of subjects enrolled	Australia: 265
Worldwide total number of subjects	350
EEA total number of subjects	85

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)	350
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment
Recruitment details: -

Pre-assignment
Screening details: Modified intention to treat

Pre-assignment period milestones	
Number of subjects started	350
Number of subjects completed	346

Pre-assignment subject non-completion reasons	
Reason: Number of subjects	Consent withdrawn by subject: 4

Period 1	
Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Assessor[1]

Arms	
Are arms mutually exclusive?	Yes
Arm title	Exenatide
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Exenatide
Investigational medicinal product code	ATC A10BJ01
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details: Exenatide 5µg subcutaneously twice daily for 5 days or discharge, whichever is sooner	
Arm title	Standard care
Arm description: -	
Arm type	Standard care
No investigational medicinal product assigned in this arm	

Notes:

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

Justification: PROBE-design

Number of subjects in period 1[2]	Exenatide	Standard care
Started	174	172
Completed	174	172

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: 4 patients withdrew consent

Period 2

Period 2 title	7 days or discharge
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Assessor[3]

Blinding implementation details:

PROBE

Arms

Are arms mutually exclusive?	Yes
Arm title	Exenatide

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Exenatide
Investigational medicinal product code	ATC A10BJ01
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Exenatide 5µg subcutaneously twice daily for 5 days or discharge, whichever is sooner

Arm title	Standard care

Arm description: -

Arm type	Standard care

No investigational medicinal product assigned in this arm

Notes:

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

Justification: PROBE-design

Number of subjects in period 2	Exenatide	Standard care
Started	174	172
Completed	174	172

Baseline characteristics

Reporting groups	
Reporting group title	Exenatide
Reporting group description: -	
Reporting group title	Standard care
Reporting group description: -	

Reporting group values	Exenatide	Standard care	Total
Number of subjects	174	172	346
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			
median	72	71	
inter-quartile range (Q1-Q3)	61 to 80	63 to 78	-
Gender categorical Units: Subjects			
Female	50	55	105
Male	124	117	241

End points

End points reporting groups	
Reporting group title	Exenatide
Reporting group description: -	
Reporting group title	Standard care
Reporting group description: -	
Reporting group title	Exenatide
Reporting group description: -	
Reporting group title	Standard care
Reporting group description: -	

Primary: More than 8 point improvement on NIHSS or a score of 0-1	
End point title	More than 8 point improvement on NIHSS or a score of 0-1
End point description:	
End point type	Primary
End point timeframe:	
7 days or time of discharge, whichever earliest	

End point values	Exenatide	Standard care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	174	172		
Units: 1	104	97		

Statistical analyses

Statistical analysis title	Primary outcome
Comparison groups	Exenatide v Standard care
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.38
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.88

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 90 days	
Assessment type	Systematic

Dictionary used	
Dictionary name	NA
Dictionary version	0

Reporting groups	
Reporting group title	Exenatide
Reporting group description: -	
Reporting group title	Standard care
Reporting group description: -	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Not available.

Serious adverse events	Exenatide	Standard care	
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 174 (14.94%)	29 / 172 (16.86%)	
number of deaths (all causes)	10	8	
number of deaths resulting from adverse events			
Investigations			
All other SAE			
subjects affected / exposed	16 / 174 (9.20%)	21 / 172 (12.21%)	
occurrences causally related to treatment / all	0 / 16	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	10 / 174 (5.75%)	8 / 172 (4.65%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 10	0 / 8	

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

Non-serious adverse events	Exenatide	Standard care	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 174 (0.00%)	0 / 172 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 October 2018	Version 3: 9 October 2018

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported