Clinical trial results:
GLP-1 ANALOGS FOR NEUROPROTECTION AFTER OUT-OF-HOSPITAL CARDIAC ARREST, A RANDOMIZED CLINICAL TRIAL

Summary

EudraCT number	2013-004311-45
Trial protocol	DK
Global end of trial date	01 June 2016

Results information

Result version number	v1 (current)
This version publication date	30 November 2021
First version publication date	30 November 2021

Trial information

Trial identification

Sponsor protocol code	2013-PharmaCA-001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Copenhagen University Hospital Rigshospitalet
Sponsor organisation address	9 Blegdamsvej, Copenhagen, Denmark, 2100
Public contact	Cardiology Intensive Care Unit B214, Copenhagen University Hospital Rigshospitalet, Department of Cardiology B 2143, 45 35452143, jesper.kjaergaard.01@regionh.dk
Scientific contact	Cardiology Intensive Care Unit B214, Copenhagen University Hospital Rigshospitalet, Department of Cardiology B 2143, 45 35452143, jesper.kjaergaard.01@regionh.dk

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	20 December 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 November 2015
Global end of trial reached?	Yes
Global end of trial date	01 June 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To reduce to degree of post anoxic brain injury following resuscitation cardiac arrest, defined by a combined endpoint of efficacy (area under the Neuron Specific Enolasis -curve) and a feasibility defined as rapid initiation of study drug infusion

Protection of trial subjects:

Was applied according to the protocol

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 January 2014
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	Denmark: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

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)	20
From 65 to 84 years	80
85 years and over	20

Subject disposition

Recruitment

Recruitment details:

Recruitment finalaized

Pre-assignment

Screening details:

Screening patients admitted after resuscitated cardiac arrest

Pre-assignment period milestones

Number of subjects started	120
Number of subjects completed	120

Period 1

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

Arms

Arm title	GLP-1 analoug

Arm description:

Byetta

Arm type	Experimental
Investigational medicinal product name	Byetta
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

17.4 mcg of exenatide

Number of subjects in period 1	GLP-1 analoug
Started	120
Completed	120

Baseline characteristics

Reporting groups	
Reporting group title	GLP-1 analoug
Reporting group description:	
Byetta	

Reporting group values	GLP-1 analoug	Total	
Number of subjects	120	120	
Age categorical			
Age groups			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	20	20	
From 65-84 years	80	80	
85 years and over	20	20	
Age continuous			
Age groups 2			
Units: years			
arithmetic mean	60		
standard deviation	± 11	-	
Gender categorical			
Gender			
Units: Subjects			
Female	22	22	
Male	98	98	

Subject analysis sets	
Subject analysis set title	final
Subject analysis set type	Full analysis
Subject analysis set description:	
Alle subjects	

Reporting group values	final		
Number of subjects	120		
Age categorical			
Age groups			
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)	20		
From 65-84 years	80		
85 years and over	20		
Age continuous			
Age groups 2			
Units: years			
arithmetic mean	60		
standard deviation	± 11		
Gender categorical			
Gender			
Units: Subjects			
Female	22		
Male	98		

End points

End points reporting groups	
Reporting group title	GLP-1 analoug
Reporting group description: Byetta	
Subject analysis set title	final
Subject analysis set type	Full analysis
Subject analysis set description: Alle subjects	

Primary: Area Under the NSE curve	
End point title	Area Under the NSE curve
End point description: Area under the NSE curve	
End point type	Primary
End point timeframe: 48 hours	

End point values	GLP-1 analoug	final		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	118	118[1]		
Units: mcg				
number (confidence interval 0%)	1307 (884 to 2093)	1307 (884 to 2093)		

Notes:
[1] - Correct

Statistical analyses

Statistical analysis title	Primary
Comparison groups	GLP-1 analoug v final
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	1307
Confidence interval	
level	95 %
sides	2-sided
lower limit	804
upper limit	2093
Variability estimate	Standard error of the mean

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 3 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	CRF
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

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: Done

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/27838646