



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 Enolase -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 finalized

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 analogue |
| 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 analogue |
| 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>