



Clinical trial results: CLOpidogrel response and CYP2C19 Genotype in Ischemic Stroke patients

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2015-003548-38 |
| Trial protocol | DK |
| Global end of trial date | 17 August 2017 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 12 December 2020 |
| First version publication date | 12 December 2020 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | 2015-1CR |
|-----------------------|----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Zealand University Hospital |
| Sponsor organisation address | Sygehusvej 10, Roskilde, Denmark, 4000 |
| Public contact | Neurologisk Afdeling, Roskilde Syge, Neurologisk Afdeling, Roskilde Sygehus, +45 47322800, |
| Scientific contact | Neurologisk Afdeling, Roskilde Syge, Neurologisk Afdeling, Roskilde Sygehus, +45 47322800, |

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 | 17 August 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 17 August 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 17 August 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Is there a connection between single nucleotide polymorphisms of liver enzyme CYP2C19 and the high on treatment platelet reactivity (HOTPR) when treating with Clopidogrel (Clopidogrel-respons) in different doses.

Protection of trial subjects:

No specific measures. Patients delivered a blood sample.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------|
| Actual start date of recruitment | 24 May 2016 |
| 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: 103 |
| Worldwide total number of subjects | 103 |
| EEA total number of subjects | 103 |

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) | 37 |
| From 65 to 84 years | 62 |
| 85 years and over | 4 |

Subject disposition

Recruitment

Recruitment details:

All adults over the age of 18 with a diagnosis of ischemic stroke and treated with clopidogrel once daily were recruited after informed verbal and written signed consent.

Pre-assignment

Screening details:

All patient with a diagnosis of ischemic stroke were screened by a physician

Period 1

| | |
|------------------------------|-----------------------------|
| Period 1 title | Overall trial |
| Is this the baseline period? | Yes |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|-----------|------------------|
| Arm title | Study population |
|-----------|------------------|

Arm description:

All patients in the trail. All had clopidogrel as a standard of care and all had a blood sample.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | clopidogrel |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

75 mg orally once daily

| | |
|--------------------------------|------------------|
| Number of subjects in period 1 | Study population |
| Started | 103 |
| Completed | 103 |

Period 2

| | |
|------------------------------|-----------------------------|
| Period 2 title | trial |
| Is this the baseline period? | No |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|---|-----------------|
| Arm title | genotype |
| Arm description: - | |
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |

| | |
|---------------------------------------|----------|
| Number of subjects in period 2 | genotype |
| Started | 103 |
| Completed | 103 |

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

| Reporting group values | Overall trial | Total | |
|---|---------------|-------|--|
| Number of subjects | 103 | 103 | |
| 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) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 37 | 37 | |
| From 65-84 years | 62 | 62 | |
| 85 years and over | 4 | 4 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 41 | 41 | |
| Male | 62 | 62 | |

End points

End points reporting groups

| | |
|--|------------------|
| Reporting group title | Study population |
| Reporting group description: All patients in the trial. All had clopidogrel as a standard of care and all had a blood sample. | |
| Reporting group title | genotype |
| Reporting group description: - | |

Primary: responder and genotype

| | |
|--|------------------------|
| End point title | responder and genotype |
| End point description: | |
| End point type | Primary |
| End point timeframe: Instantly after bloodsampling using POC-device | |

| End point values | Study population | genotype | | |
|-----------------------------|------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 103 | 103 ^[1] | | |
| Units: 2 | | | | |
| responder | 103 | 0 | | |
| nonresponder | 0 | 0 | | |
| carrier | 0 | 31 | | |
| non-carrier | 0 | 70 | | |

Notes:

[1] - 101

Statistical analyses

| | |
|---|-------------------------------|
| Statistical analysis title | responder and CYP2C19 carrier |
| Comparison groups | Study population v genotype |
| Number of subjects included in analysis | 206 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | Wilcoxon (Mann-Whitney) |

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From inclusion to last blood sampling

Adverse event reporting additional description:

There were no serious or non-serious adverse events. This was because there were no non-responders to 75 mg clopidogrel once daily and therefore no subject were followed in the study. There was no intervention

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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|-----------------|-----|
| Dictionary name | ICD |
|-----------------|-----|

| | |
|--------------------|----|
| Dictionary version | 10 |
|--------------------|----|

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | All subjects |
|-----------------------|--------------|

Reporting group description: -

| Serious adverse events | All subjects | | |
|---|-----------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 103 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

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

| Non-serious adverse events | All subjects | | |
|---|-----------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 103 (0.00%) | | |

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: Alle forsøgsparticipanter var respondere på clopidogrel 75 mg dagligt. Derfor blev alle forsøgsparticipanter afsluttet ved første besøg. Der var ingen intervention, ingen forsøgsparticipanter blev fulgt og derfor ingen adverse events.

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