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 trail. 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 inklusion to last blood sampling

Adverse event reporting additional description:

The were np seroius og 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

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 forsøgsdetalgere var respondere på clopidogrel 75 mg dagligt. Derfor blev alle forsøgsdeltagere afsluttet ved første besøg. Der var ingen intervention, ingen forsøgsdeltagere 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