Clinical trial results:
A prospective, randomized, parallel-group, open label, non-inferiority, multicenter trial of a 12 month vs. a short-term platelet function testing guided prasugrel therapy in acute coronary syndrome patients undergoing coronary stenting

Summary

EudraCT number	2013-001636-22
Trial protocol	DE HU AT PL
Global end of trial date	15 May 2017

Results information

Result version number	v1 (current)
This version publication date	27 July 2018
First version publication date	27 July 2018
Summary attachment (see zip file)	Clinical Study Report (180508_TROPICALACS_Clinical Study Report_signed.pdf)

Trial information

Trial identification

Sponsor protocol code	TROPICALACS

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01959451
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hospital of the University of Munich, Grosshadern
Sponsor organisation address	Marchioninistr.15, Munich, Germany,
Public contact	I. Med. Klinik und Poliklinik, Hospital of the University of Munich, Grosshadern, +49 89440072371,
Scientific contact	I. Med. Klinik und Poliklinik, Hospital of the University of Munich, Grosshadern, +49 89440072371,

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	08 May 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 May 2017
Global end of trial reached?	Yes
Global end of trial date	15 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

A Platelet function testing guided approach with a short-term (1 week) post hospital discharge prasugrel maintenance dose treatment and a switch-over to clopidogrel treatment in adequate responders to the drug is non-inferior to the currently recommended long-term (12 month) treatment with prasugrel in ACS patients undergoing PCI.

Protection of trial subjects:

Every subject participating in the trial was insured against any trial-related illness/injuries pursuant to the legal requirements which may occur during the trial.

Name of Insurer: HDI-Gerling Industrieversicherung AG
Insurance Number: 39 130537 03026
Address: Niederlassung Dusseldorf
Am Schönenkamp 45, D-40599 Dusseldorf
Phone: +49 (0)211/7482-5419
Fax: +49 (0)211/7482-465

This insurance covered trial related injuries to health up to a maximum of 500.000 Euro per subject.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 November 2013
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	Germany: 1440
Country: Number of subjects enrolled	Hungary: 878
Country: Number of subjects enrolled	Austria: 72
Country: Number of subjects enrolled	Poland: 220
Worldwide total number of subjects	2610
EEA total number of subjects	2610

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)	1821
From 65 to 84 years	789
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

see document attached

Pre-assignment

Screening details:

Patients with an ACS (positive for troponin) after successful percutaneous coronary intervention with an indication for standard treatment of 12 month with prasugrel.

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Guided de-escalation

Arm description:

Guided de-escalation of DAPT

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:

p.o.

Arm title	Control

Arm description:

control group

Arm type	Placebo
Investigational medicinal product name	Prasugrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

p.o.

Number of subjects in period 1	Guided de-escalation	Control
Started	1304	1306
Completed	1304	1306

Baseline characteristics

End points

End points reporting groups	
Reporting group title	Guided de-escalation
Reporting group description: Guided de-escalation of DAPT	
Reporting group title	Control
Reporting group description: control group	

Primary: primary endpoint	
End point title	primary endpoint
End point description:	
End point type	Primary
End point timeframe: 12 months	

End point values	Guided de-escalation	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1304	1306		
Units: numbers	95	118		

Statistical analyses

Statistical analysis title	kaplan meier
Statistical analysis description: ´Kaplan meier	
Comparison groups	Guided de-escalation v Control
Number of subjects included in analysis	2610
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
P-value	< 0.05
Method	Fisher exact

Notes:
[1] - non-inferiority

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: within 24 hours	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16-20.1

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

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: please see document attached

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