Clinical trial results:
BOne marrOw transfer to enhance ST-elevation infarct regeneration-2

Summary

EudraCT number	2005-000774-46
Trial protocol	DE
Global end of trial date	24 June 2016

Results information

Result version number	v1 (current)
This version publication date	16 September 2021
First version publication date	16 September 2021
Summary attachment (see zip file)	Study Report (CSR_BOOST2_final_10 Apr 2017.pdf)

Trial information

Trial identification

Sponsor protocol code	BOOST-2

Additional study identifiers

ISRCTN number	ISRCTN17457407
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hannover Medical School
Sponsor organisation address	Carl-Neuberg-Str. 1, Hannover, Germany, 30625
Public contact	Zentrum für Klinische Studien, Hannover Medical School, EudraCT@mh-hannover.de
Scientific contact	Prof. Dr. K. Wollert, Hannover Medical School, EudraCT@mh-hannover.de

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	10 April 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 June 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

- To demonstrate the efficacy of low-dose intracoronary bone marrow cell (BMC) therapy in improving left ventricular function (left ventricular ejection fraction, LVEF) determined by magnetic resonance imaging (MRI) in patients with ST-elevation myocardial infarction (STEMI) at 6 months.

- To demonstrate the efficacy of radiated BMC prior to intracoronary BMC therapy in improving left ventricular function determined by MRI in patients with ST elevation myocardial infarction at 6 months.

Protection of trial subjects:

not applicable

Background therapy:

Previous regular cardiovascular medication was reported by 23 to 44% of patients: beta-blockers (8 to 24%), ACE inhibitors (5 to 19%) and statins (3 to 18%)
The cardiovascular medication given during the initial hospital course is summarised in Table 14.; all patients received ASS, and all but one had statin treatment. Further cardiovascular drugs that were given to the great majority of patients were ACE inhibitors, beta-blockers, and clopidogrel. Another frequently prescribed cardiovascular medication were aldosterone inhibitors (roughly one third of patients). For details see Table 14. During the course of the study this picture did not change essentially. A summary of regular cardiovascular medication at week 6, month 6 and 18 is provided in Table 20.
For the Safety Population, the respective information about cardiovascular medication is presented in Tables 13, 15 and 21.

Evidence for comparator:

none

Actual start date of recruitment	06 February 2006
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: 171
Country: Number of subjects enrolled	Norway: 17
Worldwide total number of subjects	188
EEA total number of subjects	188

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)	149
From 65 to 84 years	39
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

06.02.2006 to 26.04.2016

Pre-assignment

Screening details:

patients with acute myocardial infarction

Period 1

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

Arms

Arm title	All bone marrow

Arm description:

Please see CSR and publication attached for details

Arm type	Experimental
Investigational medicinal product name	Bone Marrow (autolog iBMC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Infusion

Dosage and administration details:

Bone marrow transplantation (infusion)

Number of subjects in period 1	All bone marrow
Started	188
Completed	188

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	188	188	
Age categorical			
Older 30 years. Please see CSR and publication attached for details			
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)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Älter 30 Jahre	188	188	
Gender categorical			
It is not an endpoint of the study to evaluate gender specific differences of intracoronary BMC therapy after AMI. Therefore consecutive patients will be included in the study, irrespective of their gender. It is expected, that the gender distribution in the study will reflect the gender distribution of the appearance of myocardial infarction, although this assumption might not be fulfilled in the trial. Please see CSR and publication attached for details.			
Units: Subjects			
Female	94	94	
Male	94	94	

End points

End points reporting groups

Reporting group title	All bone marrow
Reporting group description:	
Please see CSR and publication attached for details	

Primary: Change in LVEF from base line to 6 months

End point title	Change in LVEF from base line to 6 months[1]
End point description:	
Please see CSR and publication attached for details	
End point type	Primary
End point timeframe:	
6 months after base line	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Please see CSR and publication attached for details.

End point values	All bone marrow			
Subject group type	Reporting group			
Number of subjects analysed	188[2]			
Units: MRI				
least squares mean (standard deviation)				
BMC	0 (± 0)			

Notes:

[2] - please see CSR attached for more information

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

24h
Adverse events (AE) need to be documented up to 6 weeks after randomization
Serious adverse events (SAE) need to be documented throughout the 18 months follow-up period

Adverse event reporting additional description:

Serious adverse events (SAE) need to be documented throughout the 18 months follow-up period. An electronic AE-case report form needs to be completed and e-mailed to IST GmbH and faxed to PD Dr. Kai C. Wollert within 24 hours of occurrence.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10

Frequency threshold for reporting non-serious adverse events: 0 %

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 CSR and publication attached for details.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 July 2007	Amendment 1 zu Prüfplan V7; Genehmigung PEI 25.10.2007
09 August 2010	Amendment 2 zu Prüfplan V7; Genehmigung PEI am 06.09.2010

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
02 February 2012	The recruitement of the trial has been halted due to organizational reasons: supply of excipient PBS to manufacturer of verum (MHH-CTC) has been terminated by manufacturer of PBS (Baxter)	23 February 2012

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

patient enrolment slower than expected; majority of patients screened for the trial, LVEF was only slightly reduced; patient population developed only modest adverse LV remodelling and had a good prognosis 6 months after PCI;

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28431003