Clinical trial results:
Percutaneous Intramyocardial Cell Therapy After Acute Myocardial Infarction using Bone Marrow Mononuclear Cells</full-title-trial

Summary

EudraCT number	2008-004625-42
Trial protocol	DE
Global end of trial date	02 November 2016

Results information

Result version number	v1 (current)
This version publication date	07 October 2020
First version publication date	07 October 2020
Summary attachment (see zip file)	2008-004625-42-#1777-AlsterStemCells final report (2008-004625-42-#1777-AlsterStemCells final report.docx)

Trial information

Trial identification

Sponsor protocol code	KardioPII

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Asklepios Kliniken Hamburg GmbH
Sponsor organisation address	Ruebenkamp 226, Hamburg, Germany, 22307
Public contact	Dr. Kai Jaquet, ASKLEPIOS proresearch, k.jaquet@asklepios.com
Scientific contact	Dr. Kai Jaquet, ASKLEPIOS proresearch, k.jaquet@asklepios.com

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	25 October 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 October 2010
Global end of trial reached?	Yes
Global end of trial date	02 November 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Can transendocardial injection of BMNC be used safely in patients with symptomatic heart failure?

Protection of trial subjects:

Bone marrow aspiration as well as minimal invasive catheter based mapping and cell injection procedure of/into left ventricle were performed under sedation.

Background therapy:

Besides cell therapy treatment patients received optimal standard cardiologic therapy (medication) according to at that time validated medical guidelines.

Evidence for comparator:

The results were compared to a matched control group of revascularised, post-STEMI patients with optimal standard therapy.

Actual start date of recruitment	15 January 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 23
Worldwide total number of subjects	23
EEA total number of subjects	23

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)	21

From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Between January 2009 and July 2010 all patients admitted to the cardiology department at St. Georg Hospital for acute STEMI were assessed regarding EF following successful revascularisation by pri¬mary percutaneous coronary intervention (PCI). Patients aged <80 years and baseline measurements of EF <45% (CMR) assessed at least one week after PCI wi

Pre-assignment

Screening details:

EF <45% (CMR) assessed at least one week after PCI with additional symptoms of heart failure (NYHA Class ≥II) as well as NT-proBNP levels >250 pg/ml despite successful revascularisation were eligible.

Pre-assignment period milestones

Number of subjects started	23
Number of subjects completed	23

Period 1

Period 1 title	screening period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	cell therapy arm

Arm description:

Patients receiving BMNC cell therapy.

Arm type	Active comparator
Investigational medicinal product name	Bone marrow mononuclear cells (BMNC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Intramuscular use, Percutaneous use

Dosage and administration details:

15-20 injections of concentrated BMNC (100 µl each) were performed; in total, 220±42*106 cells/patient were injected.

Arm title	control group

Arm description:

control group

Arm type	Active comparator
Investigational medicinal product name	non-treated control group
Investigational medicinal product code	
Other name	control group
Pharmaceutical forms	Injection
Routes of administration	Intracardiac use

Dosage and administration details:

This is the "Placebo Group". Ethical committee prohibited injection of placebo (saline). Therefore this is a non-treatment goup.

Number of subjects in period 1	cell therapy arm	control group
Started	12	11
Completed	12	11

Baseline characteristics

End points

End points reporting groups	
Reporting group title	cell therapy arm
Reporting group description: Patients receiving BMNC cell therapy.	
Reporting group title	control group
Reporting group description: control group	

Primary: increase of EF	
End point title	increase of EF
End point description: Significant increase of EF (+7.9±1.5%, p=0.001) while the control group showed no Change.	
End point type	Primary
End point timeframe: 12 months	

End point values	cell therapy arm	control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percent volume/volume				
arithmetic mean (standard deviation)	7.9 (± 1.5)	7.9 (± 1.5)		

Statistical analyses

Statistical analysis title	non-parametric Wilcoxon rank-sum test
Statistical analysis description: Significance within each group (cell therapy, control group) was assessed by the Kolmogorov-Smirnov test followed by a one-sample t-test with "no change" (Δ=0) as the hypothetical value. Significance of ΔEF between the groups was analysed by the non-parametric Wilcoxon rank-sum test.	
Comparison groups	cell therapy arm v control group
Number of subjects included in analysis	23
Analysis specification	Post-hoc
Analysis type	superiority
P-value	≤ 0.05
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 12 months	
Adverse event reporting additional description: During visit after 6 and 12 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	ClinicalTrials.gov
Dictionary version	PRS

Reporting groups	
Reporting group title	cell therapy group
Reporting group description: Group of patients receiving cell therapy	

Serious adverse events	cell therapy group		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 12 (16.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
decompensated heart failure			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
PCI	Additional description: percutaneous coronary intervention 8 months after cell therapy		
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	cell therapy group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 12 (25.00%)		
Cardiac disorders			

non-serious cardiac adverse event	Additional description: non-serious cardiac adverse events: ventricular tachycardia (unrelated/unlikely) occurred in 3 patients		
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	3		

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