Clinical trial results:
A prospective, double blind, randomized, placebo-controlled clinical trial of intracoronary infusion of immunoselected, bone marrow-derived Stro3 mesenchymal precursor cells (MPC) in the treatment of patients with ST-elevation myocardial infarction

Summary

EudraCT number	2010-020497-41
Trial protocol	GB BE NL DK SE CZ AT PL IT ES PT
Global end of trial date	06 April 2021

Results information

Result version number	v1 (current)
This version publication date	25 February 2023
First version publication date	25 February 2023

Trial information

Trial identification

Sponsor protocol code	ANG.AMI-IC001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01781390
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Mesoblast, Inc.
Sponsor organisation address	5 New Street Square, London, United Kingdom, EC4A 3TW
Public contact	Clinical Trials Information, Mesoblast Limited , +61 396396036, clinical@mesoblast.com
Scientific contact	Clinical Trials Information, Mesoblast Limited , +61 396396036, clinical@mesoblast.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	06 April 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 April 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to determine the safety and feasibility of intracoronary allogeneic, immuno-selected, bone marrow-derived Stro3 mesenchymal precursor cell (MPC) delivery in the treatment of subjects with ST-elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention of the left anterior descending coronary artery (LAD).

Protection of trial subjects:

The study was conducted in accordance with the ethical principles stated in the Declaration of Helsinki and the International Council on Harmonization (ICH) Guideline for Good Clinical Practice (GCP). In addition, the study was overseen by an Independent Data and Safety Monitoring Board.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 March 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	Netherlands: 3
Country: Number of subjects enrolled	Poland: 23
Country: Number of subjects enrolled	Portugal: 3
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Sweden: 25
Country: Number of subjects enrolled	United Kingdom: 10
Country: Number of subjects enrolled	Australia: 11
Country: Number of subjects enrolled	New Zealand: 2
Country: Number of subjects enrolled	Czechia: 19
Country: Number of subjects enrolled	Denmark: 5
Worldwide total number of subjects	103
EEA total number of subjects	80

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	66
From 65 to 84 years	37
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects with a diagnosis of ST-elevation myocardial infarction were randomized in 1:1:1 to receive either 12.5 Million or 25 Million MPCs or placebo (saline).

Pre-assignment period milestones

Number of subjects started	106[1]
Number of subjects completed	103

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Subjects who were Randomized and Not Treated: 3

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 106 subjects were randomized in the study out of which 3 subjects were not treated.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received matching-placebo solution 2 milliliters per minute (mL/min) infused intracoronary for 60 min including line flush [0 Mesenchymal Precursor Cells (MPCs)/min] on Day 0.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intracoronary use

Dosage and administration details:

Matching-placebo solution 2 milliliter per minute (mL/min) infused Intracoronary.

Arm title	Mesenchymal Precursor Cells (MPC) 12.5 M

Arm description:

Subjects received MPC 12.5 solution 2 mL/min infused intracoronary for 60 min including line flush (2.5x10^5 MPCs/min) on Day 0.

Arm type	Experimental
Investigational medicinal product name	Mesenchymal Precursor Cells (MPC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intracoronary use

Dosage and administration details:

MPC 12.5 solution 2 mL/min infused Intracoronary for 60 min

Arm title	Mesenchymal Precursor Cells (MPC) 25 M

Arm description:

Subjects received MPC 12.5 solution 2 mL/min infused intracoronary for 60 min including line flush (5.0x10^5 MPCs/min) on Day 0.

Arm type	Experimental
Investigational medicinal product name	Mesenchymal Precursor Cells (MPC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intracoronary use

Dosage and administration details:

MPC 25 solution 2 mL/min infused Intracoronary for 60 min

Number of subjects in period 1	Placebo	Mesenchymal Precursor Cells (MPC) 12.5 M	Mesenchymal Precursor Cells (MPC) 25 M
Started	34	34	35
Completed	32	28	32
Not completed	2	6	3
Withdrawal of Consent	-	3	1
Adverse Event	1	2	1
Lost to follow-up	1	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received matching-placebo solution 2 milliliters per minute (mL/min) infused intracoronary for 60 min including line flush [0 Mesenchymal Precursor Cells (MPCs)/min] on Day 0.	
Reporting group title	Mesenchymal Precursor Cells (MPC) 12.5 M
Reporting group description:	
Subjects received MPC 12.5 solution 2 mL/min infused intracoronary for 60 min including line flush (2.5x10^5 MPCs/min) on Day 0.	
Reporting group title	Mesenchymal Precursor Cells (MPC) 25 M
Reporting group description:	
Subjects received MPC 12.5 solution 2 mL/min infused intracoronary for 60 min including line flush (5.0x10^5 MPCs/min) on Day 0.	

Reporting group values	Placebo	Mesenchymal Precursor Cells (MPC) 12.5 M	Mesenchymal Precursor Cells (MPC) 25 M
Number of subjects	34	34	35
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	61.3	60.7	57.6
standard deviation	± 9.79	± 13.11	± 12.12
Gender categorical Units: Subjects			
Female	7	2	8
Male	27	32	27
Ethnicity Units: Subjects			
Hispanic or Latino	1	1	0
Not Hispanic or Latino	33	33	35
Unknown or Not Reported	0	0	0
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0

Black or African American	0	0	0
White	33	33	34
More than one race	0	0	0
Unknown or Not Reported	0	1	1
Left Ventricular (LV) End-systolic Volume (LVESV) as Assessed by Cardiac MRI			
Full analysis population included all subjects who were randomized, underwent PCI and had infusion of study product initiated as randomized. Number analyzed are the number of subjects with data available for LVESV at Baseline. Baseline is defined as value measured at Day 2 to 4.			
Units: milliliter (ml)			
arithmetic mean	85.544	91.728	92.163
standard deviation	± 34.8935	± 30.4476	± 33.1251

Reporting group values	Total		
Number of subjects	103		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	17		
Male	86		
Ethnicity Units: Subjects			
Hispanic or Latino	2		
Not Hispanic or Latino	101		
Unknown or Not Reported	0		
Race Units: Subjects			
American Indian or Alaska Native	0		
Asian	1		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	100		
More than one race	0		
Unknown or Not Reported	2		

Left Ventricular (LV) End-systolic Volume (LVESV) as Assessed by Cardiac MRI			
Full analysis population included all subjects who were randomized, underwent PCI and had infusion of study product initiated as randomized. Number analyzed are the number of subjects with data available for LVESV at Baseline. Baseline is defined as value measured at Day 2 to 4.			
Units: milliliter (ml)			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects received matching-placebo solution 2 milliliters per minute (mL/min) infused intracoronary for 60 min including line flush [0 Mesenchymal Precursor Cells (MPCs)/min] on Day 0.	
Reporting group title	Mesenchymal Precursor Cells (MPC) 12.5 M
Reporting group description:	
Subjects received MPC 12.5 solution 2 mL/min infused intracoronary for 60 min including line flush (2.5x10^5 MPCs/min) on Day 0.	
Reporting group title	Mesenchymal Precursor Cells (MPC) 25 M
Reporting group description:	
Subjects received MPC 12.5 solution 2 mL/min infused intracoronary for 60 min including line flush (5.0x10^5 MPCs/min) on Day 0.	

Primary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)[1]
End point description:	
The safety set included all randomized subjects who received treatment.	
End point type	Primary
End point timeframe:	
Up to approximately 8 years	

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: No statistical analysis was conducted for this endpoint.

End point values	Placebo	Mesenchymal Precursor Cells (MPC) 12.5 M	Mesenchymal Precursor Cells (MPC) 25 M	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	35	
Units: subjects				
TEAEs	28	30	31	
SAEs	14	16	14	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to approximately 8 years	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received matching-placebo solution 2 milliliters per minute (mL/min) infused intracoronary for 60 min including line flush [0 Mesenchymal Precursor Cells (MPCs)/min] on Day 0.	
Reporting group title	Mesenchymal Precursor Cells (MPC) 12.5 M
Reporting group description:	
Subjects received MPC 12.5 solution 2 mL/min infused intracoronary for 60 min including line flush (2.5x10^5 MPCs/min) on Day 0.	
Reporting group title	Mesenchymal Precursor Cells (MPC) 25 M
Reporting group description:	
Subjects received MPC 12.5 solution 2 mL/min infused intracoronary for 60 min including line flush (5.0x10^5 MPCs/min) on Day 0.	

Serious adverse events	Placebo	Mesenchymal Precursor Cells (MPC) 12.5 M	Mesenchymal Precursor Cells (MPC) 25 M
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 34 (41.18%)	16 / 34 (47.06%)	14 / 35 (40.00%)
number of deaths (all causes)	0	2	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stromal tumour			

subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Thyroid adenoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	3 / 35 (8.57%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent thrombosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			

subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Angina pectoris			
subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriospasm coronary			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			

subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	2 / 34 (5.88%)	3 / 34 (8.82%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine with aura			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Diaphragmatic hernia gangrenous			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 34 (2.94%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urosepsis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypovolaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo	Mesenchymal Precursor Cells (MPC) 12.5 M	Mesenchymal Precursor Cells (MPC) 25 M
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 34 (76.47%)	30 / 34 (88.24%)	30 / 35 (85.71%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	3 / 35 (8.57%)
occurrences (all)	2	1	3
Hypotension			
subjects affected / exposed	2 / 34 (5.88%)	4 / 34 (11.76%)	1 / 35 (2.86%)
occurrences (all)	2	4	1
Peripheral coldness			
subjects affected / exposed	1 / 34 (2.94%)	4 / 34 (11.76%)	1 / 35 (2.86%)
occurrences (all)	1	5	1
Aortic dilatation			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0

Peripheral artery occlusion			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Catheter site haematoma			
subjects affected / exposed	1 / 34 (2.94%)	2 / 34 (5.88%)	1 / 35 (2.86%)
occurrences (all)	1	2	1
Chest pain			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	3 / 35 (8.57%)
occurrences (all)	1	1	4
Fatigue			
subjects affected / exposed	2 / 34 (5.88%)	3 / 34 (8.82%)	1 / 35 (2.86%)
occurrences (all)	3	5	1
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	2 / 34 (5.88%)	6 / 34 (17.65%)	3 / 35 (8.57%)
occurrences (all)	2	7	4
Oedema peripheral			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	2 / 35 (5.71%)
occurrences (all)	0	2	2
Pyrexia			
subjects affected / exposed	5 / 34 (14.71%)	2 / 34 (5.88%)	3 / 35 (8.57%)
occurrences (all)	5	2	3
Chest discomfort			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	1	0	1
Asthenia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Medical device site rash			

subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Pseudophakodonesis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	2 / 35 (5.71%)
occurrences (all)	2	0	2
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	2	0	0
Rales			
subjects affected / exposed	2 / 34 (5.88%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	3	1	0
Cough			
subjects affected / exposed	2 / 34 (5.88%)	2 / 34 (5.88%)	5 / 35 (14.29%)
occurrences (all)	3	2	5
Dyspnoea			
subjects affected / exposed	2 / 34 (5.88%)	8 / 34 (23.53%)	2 / 35 (5.71%)
occurrences (all)	2	11	3
Epistaxis			
subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	2	0	1
Asthma			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	4	0
Dyspnoea exertional			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	1	0	1
Sleep apnoea syndrome			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	1	1	0
Pleural effusion			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Pulmonary congestion			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Respiratory failure			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Respiratory tract inflammation			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 34 (2.94%)	2 / 34 (5.88%)	1 / 35 (2.86%)
occurrences (all)	1	2	1
Insomnia			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	2 / 35 (5.71%)
occurrences (all)	1	1	2
Claustrophobia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Initial insomnia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0

Investigations			
Blood triglycerides increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Cardiac murmur			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Haemoglobin decreased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Blood creatinine increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Body temperature increased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Electrocardiogram T wave normal			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Gastric pH decreased			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Heart rate irregular			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Inflammatory marker increased			

subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Liver function test increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Monoclonal immunoglobulin present			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Platelet count increased			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	0	2	0
Post procedural haematoma			
subjects affected / exposed	4 / 34 (11.76%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	4	1	0
Arthropod sting			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Hand fracture			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Radius fracture			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Rib fracture			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Road traffic accident			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Wound			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Congenital cystic kidney disease			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	2
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	2 / 34 (5.88%)	3 / 34 (8.82%)	1 / 35 (2.86%)
occurrences (all)	3	3	1
Arteriospasm coronary			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 34 (2.94%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	1	2	0
Bradycardia			
subjects affected / exposed	1 / 34 (2.94%)	2 / 34 (5.88%)	2 / 35 (5.71%)
occurrences (all)	1	2	3
Cardiac failure			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	3 / 35 (8.57%)
occurrences (all)	1	1	3
Cardiac ventricular thrombosis			
subjects affected / exposed	1 / 34 (2.94%)	4 / 34 (11.76%)	0 / 35 (0.00%)
occurrences (all)	1	4	0
Palpitations			
subjects affected / exposed	0 / 34 (0.00%)	3 / 34 (8.82%)	1 / 35 (2.86%)
occurrences (all)	0	4	1
Pericarditis			

subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	3 / 35 (8.57%)
occurrences (all)	0	1	3
Ventricular tachycardia			
subjects affected / exposed	1 / 34 (2.94%)	3 / 34 (8.82%)	5 / 35 (14.29%)
occurrences (all)	1	7	5
Atrial flutter			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	1	0	1
Intracardiac thrombus			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Pericardial effusion			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	1	0	1
Supraventricular tachycardia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	1	0	1
Arrhythmia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Bundle branch block left			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Cardiac aneurysm			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Chronotropic incompetence			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Coronary artery dissection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Dressler's syndrome			

subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Pericardial rub			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Rhythm idioventricular			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Supraventricular extrasystoles			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Ventricular extrasystoles			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 34 (11.76%)	8 / 34 (23.53%)	5 / 35 (14.29%)
occurrences (all)	5	12	5
Dizziness postural			
subjects affected / exposed	1 / 34 (2.94%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	1	2	0
Headache			
subjects affected / exposed	2 / 34 (5.88%)	1 / 34 (2.94%)	2 / 35 (5.71%)
occurrences (all)	2	1	2
Lethargy			
subjects affected / exposed	1 / 34 (2.94%)	3 / 34 (8.82%)	1 / 35 (2.86%)
occurrences (all)	1	3	1
Presyncope			
subjects affected / exposed	1 / 34 (2.94%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	1	2	0

Hypoaesthesia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Syncope			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Amnesia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Mental impairment			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Sensory disturbance			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 34 (5.88%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	2	2	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Anaemia macrocytic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Spontaneous haematoma			

subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	0	2	0
Cataract			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Macular degeneration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Periorbital oedema			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 34 (2.94%)	2 / 34 (5.88%)	2 / 35 (5.71%)
occurrences (all)	1	2	2
Constipation			
subjects affected / exposed	1 / 34 (2.94%)	5 / 34 (14.71%)	1 / 35 (2.86%)
occurrences (all)	1	5	1
Diarrhoea			
subjects affected / exposed	4 / 34 (11.76%)	3 / 34 (8.82%)	5 / 35 (14.29%)
occurrences (all)	4	3	5
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	0	4	0
Nausea			
subjects affected / exposed	1 / 34 (2.94%)	5 / 34 (14.71%)	3 / 35 (8.57%)
occurrences (all)	1	5	4
Vomiting			

subjects affected / exposed	2 / 34 (5.88%)	2 / 34 (5.88%)	3 / 35 (8.57%)
occurrences (all)	3	2	3
Dyspepsia			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	1	1	1
Abdominal discomfort			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	1	0	1
Abdominal pain upper			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	1	1	0
Abdominal hernia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Bowel movement irregularity			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Chronic gastritis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Eructation			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Gingival bleeding			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Haematochezia			

subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Rectal spasm			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Hepatic failure			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Hepatic steatosis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Liver disorder			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Cold sweat			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Renal and urinary disorders			

Dysuria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	3 / 35 (8.57%)
occurrences (all)	0	0	3
Lower urinary tract symptoms			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	0	2	0
Urinary retention			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	1	1	0
Chronic kidney disease			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Renal cyst			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Strangury			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Ureterolithiasis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hyperthyroidism			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	4 / 35 (11.43%)
occurrences (all)	0	1	5
Muscle spasms			
subjects affected / exposed	2 / 34 (5.88%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	2	1	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	2 / 35 (5.71%)
occurrences (all)	0	2	3
Musculoskeletal pain			
subjects affected / exposed	1 / 34 (2.94%)	4 / 34 (11.76%)	1 / 35 (2.86%)
occurrences (all)	1	4	1
Myalgia			
subjects affected / exposed	2 / 34 (5.88%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	2	1	0
Pain in extremity			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	2 / 35 (5.71%)
occurrences (all)	1	0	4
Arthralgia			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	1	1	1
Costochondritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Musculoskeletal discomfort			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	2	0	0
Neck pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Rheumatoid arthritis			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Spinal pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	2
Tendonitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Infections and infestations			
Influenza			
subjects affected / exposed	2 / 34 (5.88%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	2	1	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	3 / 35 (8.57%)
occurrences (all)	0	3	4
Nasopharyngitis			
subjects affected / exposed	3 / 34 (8.82%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	3	0	1
Pneumonia			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	1 / 35 (2.86%)
occurrences (all)	0	2	1
Respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	2 / 35 (5.71%)
occurrences (all)	0	1	2
Upper respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	1 / 34 (2.94%)	3 / 34 (8.82%)	0 / 35 (0.00%)
occurrences (all)	1	4	0
Bronchitis			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	1	1	0
Acute sinusitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0

Campylobacter infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Corona virus infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Eye infection			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	2	0	0
Gastroenteritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Lung infection			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	2	0	0
Onychomycosis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Pertussis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Hypokalaemia			
subjects affected / exposed	2 / 34 (5.88%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	2	1	1
Decreased appetite			

subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Diabetes mellitus			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Gout			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Hypoproteinaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Lactose intolerance			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 February 2012	The purpose of the amendment was to refine assessments, include additional events captured as Major adverse cardiac and cerebrovascular events(MACCE) to be consistent with the CEC adjudication process, clarification of AE description of the Severity and changing Causality to a binary assessment. Clarification on feasibility endpoint was also made.
24 April 2012	The purpose of the amendment was to remove termination conditions outlined in section 4.4, early termination of study and in Section 12.8 termination of study.
21 May 2012	The purpose of the amendment was to revise wording with respect to early termination of the study.
07 September 2012	The purpose of the amendment was to refine timing and type of assessments, including ECHO, ECG, Troponins, Serum Pregnancy Test, and AEs. Added footnotes to Table 2. Replaced conditions for conducting cardiac MRI at Early Termination Visit. Updated data on Human Clinical Studies. Clarified infusion time of allogeneic MPCs. Revised the frequency of providing adverse event and serious adverse event data to the DSMB. Clarified the protocol assessments and follow-up for subjects who prematurely withdrew from study. Added non-MACCE events that may be reviewed by Clinical Events Committee.
06 August 2013	The purpose of the amendment was to refine assessments, inclusion / exclusion criteria, modify solution for dilution of the MPCs and placebo. Included requirement of an intracoronary bolus of glyceryl trinitrate (GTN)/ nitroglycerin (NTG) administration prior to the initial infusion of the investigational agent. Changed primary efficacy endpoint.
13 May 2014	The purpose of the amendment was to add study hypothesis, and revise study assessments, secondary objectives, and primary efficacy endpoint. Timing of Onset of Chest Pain to Initial Balloon Inflation and stratification for randomization balancing was revised. Updated statistical analysis methods for the primary analysis.
01 August 2016	The purpose of the amendment was to update the rationale for trial size and justification that an interim analysis was not needed and was not to be performed.
11 October 2016	The purpose of the amendment was to correct the power from 90% to 80%.
04 May 2017	The purpose of the amendment was to correct power from 90% to 80%. A power of 90% was inadvertently introduced when addressing the assumptions for changing the sample size from 225 to 105 (Protocol v8).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported