



Clinical trial results: REGENERATE – AMI Summary

EudraCT number	2010-021277-36
Trial protocol	DK
Global end of trial date	08 March 2018

Results information

Result version number	v1 (current)
This version publication date	22 March 2019
First version publication date	22 March 2019
Summary attachment (see zip file)	Published (Published Paper - REGENERATE AMI.pdf)

Trial information

Trial identification

Sponsor protocol code	REGENERATE – AMI
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Queen Mary University of London
Sponsor organisation address	JRMO, 5 Walden Street, London, United Kingdom, E1 2EF
Public contact	Prof A Mathur, Queen Mary University of London, a.mathur@qmul.ac.uk
Scientific contact	Prof A Mathur, Queen Mary University of London, a.mathur@qmul.ac.uk

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	01 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 March 2014
Global end of trial reached?	Yes
Global end of trial date	08 March 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To improve post-infarction myocardial function

Protection of trial subjects:

Bone Marrow aspiration was under performed under local anaesthetic.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 March 2008
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	United Kingdom: 91
Country: Number of subjects enrolled	Switzerland: 1
Country: Number of subjects enrolled	Denmark: 8
Worldwide total number of subjects	100
EEA total number of subjects	99

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)	77
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started in March 2008 and ended in 2013 and 100 patients were recruited across 3 countries.

Pre-assignment

Screening details:

Ant MI patients with moderate regional wall abnormality on LV angiogram

Period 1

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

Arms

Arm title	Placebo
Arm description:	
Plecebo arm	
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:

10ml

Number of subjects in period 1^[1]	Placebo
Started	45
Completed	45

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Please see full report with supplementary data attached for in-depth breakdown

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	45	45	
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)	30	30	
From 65-84 years	15	15	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	4	4	
Male	41	41	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo arm	
Subject analysis set title	Placebo arm
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Change in LV function in the placebo group	
Subject analysis set title	BMC arm
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
BMC intra-coronary	

Primary: Change in Ejection Fraction at 12 month based on advanced cardiac imaging

End point title	Change in Ejection Fraction at 12 month based on advanced cardiac imaging
End point description:	
End point type	Primary
End point timeframe:	
12 months	

End point values	Placebo arm	BMC arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45 ^[1]	55 ^[2]		
Units: percentage				
number (confidence interval 95%)	2.8 (-0.5 to 5.0)	5.0 (-0.5 to 5.0)		

Notes:

[1] - Placebo

[2] - BCM

Statistical analyses

Statistical analysis title	Paired T test
Comparison groups	BMC arm v Placebo arm
Number of subjects included in analysis	100
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.1
Method	ANOVA
Parameter estimate	pvalue

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse event were reported at 3 months, 6 months and yearly.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	7
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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 full report attached for all details of 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