Clinical trial results:
Stem Cell therapy in IschEmic Non-treatable Cardiac disease - SCIENCE

Summary

EudraCT number	2015-002929-19
Trial protocol	NL DK SI DE AT PL
Global end of trial date	31 December 2022

Results information

Result version number	v1 (current)
This version publication date	19 May 2023
First version publication date	19 May 2023
Summary attachment (see zip file)	Synopsis SCIENCE (Synopsis SCIENCE clinical trial Eudra-CT.pdf) SCIENCE trial (European J of Heart Fail - 2023 - Qayyum - Effect of allogeneic adipose tissuederived mesenchymal stromal cell treatment.pdf)

Trial information

Trial identification

Sponsor protocol code	SCIENCE

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02673164
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej, Copenhagen, Denmark, 2100
Public contact	Jens Kastrup, Department of Cardiology, 2014, Rigshospitalet, 0045 35452819, jens.kastrup@regionh.dk
Scientific contact	Jens Kastrup, Department of Cardiology, 2014, Rigshospitalet, 0045 35452819, jens.kastrup@regionh.dk

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 July 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 May 2022
Global end of trial reached?	Yes
Global end of trial date	31 December 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To perform at clinical double-blind placebo-controlled CSCC_ASC multicentre study in heart failure patients to investigate the regenerative capacity of the CSCC_ASC treatment.

Protection of trial subjects:

In hospital follow-up 24 hours after treatment.

Background therapy:

Maximal tolarable medical heart failure therapy

Evidence for comparator:

No

Actual start date of recruitment	01 January 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 20
Country: Number of subjects enrolled	Slovenia: 30
Country: Number of subjects enrolled	Austria: 15
Country: Number of subjects enrolled	Denmark: 34
Country: Number of subjects enrolled	Germany: 20
Country: Number of subjects enrolled	Netherlands: 14
Worldwide total number of subjects	133
EEA total number of subjects	133

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)	58
From 65 to 84 years	75
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 133 of the planned 139 patients were included in the trial. It was not possible to prolong the inclusion period, due to finalization of the Horizon2020 grant period.

Pre-assignment

Screening details:

A total of 133 patients (122 men and 11 women) with stable symptomatic chronic ischemic HFrEF were included into the study. Approximately 2/3 of the patients were in NYHA II class and 1/3 in NYHA III in both groups.

Pre-assignment period milestones

Number of subjects started	133
Number of subjects completed	133

Period 1

Period 1 title	Baseline ASC (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

Blinding implementation details:

All participating in the clinical contact with the patients and the collected data were blinded. When all data were collected and analyzed then the code was broken by the producer of the cell and placebo vials.

Arms

Are arms mutually exclusive?	Yes
Arm title	ASC treatment

Arm description: -

Arm type	Experimental
Investigational medicinal product name	CSCC_ASC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Intramuscular use

Dosage and administration details:

Injections of 110 mio. CSCC_ASCs in 5 mL CryoStor

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Intramuscular use

Dosage and administration details:

Injections of saline

Number of subjects in period 1	ASC treatment	Placebo
Started	90	43
Completed	90	41
Not completed	0	2
dead	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Baseline ASC

Reporting group description: -

Reporting group values	Baseline ASC	Total	
Number of subjects	133	133	
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			
The mean age was 66.4 ± 8.1 years in the ASC group and 64.0 ± 8.8 years in the placebo group			
Units: years			
arithmetic mean	65.2		
standard deviation	± 8.5	-	
Gender categorical Units: Subjects			
Female	11	11	
Male	122	122	

End points

End points reporting groups	
Reporting group title	ASC treatment
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: LVESV (left ventricular end systolic volume)	
End point title	LVESV (left ventricular end systolic volume)
End point description:	
End point type	Primary
End point timeframe:	
6 months after ASC or placebo intramyocardial injections	

End point values	ASC treatment	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90	41		
Units: mL				
number (not applicable)	90	41		

Statistical analyses

Statistical analysis title	T-test
Comparison groups	ASC treatment v Placebo
Number of subjects included in analysis	131
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 6 months after ASC/placebo treatment	
Assessment type	Systematic

Dictionary used	
Dictionary name	other
Dictionary version	1

Reporting groups	
Reporting group title	ASC and Placebo

Reporting group description: -

Serious adverse events	ASC and Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 133 (3.76%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events	0		
Cardiac disorders			
1 year			
subjects affected / exposed	5 / 133 (3.76%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 5		

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

Non-serious adverse events	ASC and Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 133 (48.87%)		
Cardiac disorders			
1 year			
subjects affected / exposed	65 / 133 (48.87%)		
occurrences (all)	65		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/36644821