Clinical trial results:
Ensayo Clínico Fase II sobre el Efecto de la Infusión Intracoronaria de Células Mononucleadas de Médula Ósea Sobre la Recuperación Funcional en Pacientes con Infarto Crónico Anterior y Depresión Severa de la Función Ventricular Izquierda

Summary

EudraCT number	2009-016599-66
Trial protocol	ES
Global end of trial date	07 April 2015

Results information

Result version number	v1 (current)
This version publication date	06 March 2024
First version publication date	06 March 2024
Summary attachment (see zip file)	Final Report_Summary (SINOPSIS final CMMo_CIC_2009_DEF(F).pdf)

Trial information

Trial identification

Sponsor protocol code	CMMo/CIC/2009

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Fundación Pública Andaluza Progreso y Salud M.P.
Sponsor organisation address	Avda. Américo Vespucio 15 · Edificio S-2 · 2ª Pta, Sevilla, Spain, 41092
Public contact	ROSARIO CARMEN MATA ALCÁZAR-CABALLERO, Fundación Pública Andaluza Progreso y Salud M.P., rosario.mata@juntadeandalucia.es
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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	27 December 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 April 2015
Global end of trial reached?	Yes
Global end of trial date	07 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Determinar la eficacia de la inyección intracoronaria de células madre adultas de MO autóloga en pacientes con Infarto de Miocardio Anterior Crónico en términos de mejoría de la función ventricular, determinada por parámetros hemodinámicos, ecocardiográficos y de grado funcional de la NYHA, que se traduce en mejoría de los síntomas de insuficiencia cardiaca y de la calidad de vida del paciente

Protection of trial subjects:

The trial has been carried out in accordance with the recommendations for Clinical Trials and the evaluation of the product under investigation in humans, which appear in the Declaration of Helsinki, revised in successive world assemblies (WMA, 2008), and the current Spanish Legislation on Clinical Trials. In addition, the ICH-GPC standards have been followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 December 2010
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	Spain: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment
Recruitment details: -

Pre-assignment
Screening details: -

Pre-assignment period milestones	
Number of subjects started	20
Number of subjects completed	20

Period 1	
Period 1 title	Recruitment and follow-up (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Arm title	Group A
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Unexpanded autologous bone marrow adult mononuclear stem cells
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intracoronary use

Dosage and administration details:

5 and 7 x 10e8 total cells

Number of subjects in period 1	Group A
Started	20
Completed	20

Baseline characteristics

Reporting groups

Reporting group title	Recruitment and follow-up

Reporting group description: -

Reporting group values	Recruitment and follow-up	Total	
Number of subjects	20	20	
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	58.6		
standard deviation	± 13.35	-	
Gender categorical Units: Subjects			
Female	1	1	
Male	19	19	

End points

End points reporting groups

Reporting group title	Group A

Reporting group description: -

Primary: Efficacy

End point title	Efficacy[1]

End point description:

Determine the efficacy of intracoronary injection of bone marrow progenitor cells autologous in patients with Chronic Anterior Infarction and Heart Failure in the improvement of Ventricular function determined by hemodynamic, clinical and echocardiographic parameters.

End point type	Primary

End point timeframe:

During the study

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: It is detailed in the summary of the clinical report

End point values	Group A			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: units	20			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: From the inclusion of the first patient to the last visit of the last patient.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	NA

Frequency threshold for reporting non-serious adverse events: 1 %

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: It is detailed in the summary of the clinical report

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 January 2010	Change in the planned duration of the study
27 August 2010	Change of exclusion criteria
28 January 2011	A new version of the Sheet is generated Information and Informed Consent for angiography
20 April 2012	The recruitment period is extended to 24 months
12 June 2013	Recruitment period extended
16 December 2013	Recruitment period extended

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported