Clinical trial results:
ENSAYO CLINICO FASE II MULTICENTRICO, ABIERTO Y ALEATORIZADO SOBRE EL USO TERAPEUTICO DE LA INFUSION INTRAARTERIAL DE CÉLULAS MONONUCLEADAS DE MÉDULA ÓSEA AUTÓLOGA EN PACIENTES NO DIABÉTICOS CON ISQUEMIA CRÓNICA CRÍTICA DE MIEMBROS INFERIORES

Summary

EudraCT number	2009-013636-20
Trial protocol	ES
Global end of trial date	29 December 2022

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 Informe final RAdytTA_CMMo_ICC_2009(F).pdf)

Trial information

Trial identification

Sponsor protocol code	CMMo/ICC/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	29 December 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 December 2022
Global end of trial reached?	Yes
Global end of trial date	29 December 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluar la seguridad y factibilidad del autotrasplante de células mononucleadas de médula ósea (mo-CMNs) autóloga administradas por vía intraarterial en el miembro afecto de pacientes no diabéticos con isquemia crónica crítica de los miembros inferiores sin posibilidades de revascularización ni otras alternativas terapéuticas.

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	01 July 2009
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	Spain: 37
Worldwide total number of subjects	37
EEA total number of subjects	37

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)	37
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	28[1]
Number of subjects completed	28

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: It is detailed in the summary of the clinical report

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1

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	Intravenous use

Dosage and administration details:

1x10e8 moCMNs

Arm title	Group 2

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	Injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

5x10e8 moCMNs

Arm title	Group 3

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	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

1x10e9 moCMNs

Number of subjects in period 1[2]	Group 1	Group 2	Group 3
Started	9	11	8
Completed	9	11	8

Notes:

[2] - 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: It is detailed in the summary of the clinical report

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	28	28	
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)	20	20	
From 65-84 years	8	8	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	8	8	
Male	20	20	

End points

End points reporting groups

Reporting group title	Group 1
Reporting group description: -	
Reporting group title	Group 2
Reporting group description: -	
Reporting group title	Group 3
Reporting group description: -	

Primary: Safety and feasibility

End point title	Safety and feasibility[1]

End point description:

To evaluate the safety and feasibility of autotransplantation of mononucleated marrow cells autologous bone, administered intra-arterially in non-diabetic patients with ischemia chronic critical condition of the lower limbs without the possibility of revascularization or other therapeutic alternatives.

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 1	Group 2	Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	11	8	
Units: units	9	11	8	

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
12 November 2009	changes in the research team
29 March 2011	new participating centers are added
08 May 2012	The monitoring period is modified
10 June 2013	The sample size is decreased

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported