Clinical trial results:
Phase II Clinical Study on Therapeutic Angiogenesis with Mononucleated Autologous Bone Marrow Cells in Diabetic Patients with Chronic Critical Ischemia of non-revascularizable lower limbs

Summary

EudraCT number	2008-004064-39
Trial protocol	ES
Global end of trial date	29 September 2011

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)	Sinopsis informe final CMMo/ICPD/2008 (SINOPSIS INFORME FINAL corregida CMMO-ICPD-2008_def..pdf)

Trial information

Trial identification

Sponsor protocol code	CMMo/ICPD/2008

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Red Andaluza de Diseño y Traslación en Terapias Avanzadas (former Iniciativa Andaluza en Terapias Avanzadas) – Fundación Progreso y Salud
Sponsor organisation address	Avda. Américo Vespucio 15 · Edificio S-2 ·2ª Pta , Sevilla, Spain,
Public contact	Rosario Carmen Mata Alcázar-Caballero, Red Andaluza de Diseño y Traslación en Terapias Avanzadas (former Iniciativa Andaluza en Terapias A, +34 955 048 366, terapias.avanzadas@juntadeandalucia.es
Scientific contact	Rosario Carmen Mata Alcázar-Caballero, Red Andaluza de Diseño y Traslación en Terapias Avanzadas (former Iniciativa Andaluza en Terapias A, +34 955 048 366, terapias.avanzadas@juntadeandalucia.es

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 October 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 September 2011
Global end of trial reached?	Yes
Global end of trial date	29 September 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and feasibility of autologous mononucleated bone marrow cell transplantation (mo-MNCs) administered intra-arterially in the affected limb of diabetic patients with chronic critical ischemia of the lower limbs without possibilities of revascularization or other therapeutic alternatives.

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: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	35

From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	60
Number of subjects completed	60

Period 1

Period 1 title	Safety and feasibility (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 control

Arm description:

Conventional treatment

Arm type	Active comparator
Investigational medicinal product name	No investigational medicinal product assigned in this arm
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Not mentioned

Dosage and administration details:

NA

Arm title	Group 1

Arm description:

Autologous bone marrow mononucleated cells

Arm type	Experimental
Investigational medicinal product name	Autologous bone marrow mononucleated cells
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intraarterial use

Dosage and administration details:

1x10e8 de mo-CMNs

Arm title	Group 2

Arm description:

Autologous bone marrow mononucleated cells

Arm type	Experimental

Investigational medicinal product name	Autologous bone marrow mononucleated cells
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intraarterial use

Dosage and administration details:
5x10e8 de mo-CMNs

Arm title	Group 3

Arm description:
Autologous bone marrow mononucleated cells

Arm type	Experimental
Investigational medicinal product name	No investigational medicinal product assigned in this arm
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Not mentioned

Dosage and administration details:
NA

Investigational medicinal product name	Autologous bone marrow mononucleated cells
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intraarterial use

Dosage and administration details:
1x10e9 de mo-CMNs

Number of subjects in period 1	Group control	Group 1	Group 2
Started	15	15	15
Completed	15	15	15

Number of subjects in period 1	Group 3
Started	15
Completed	15

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group control
Reporting group description: Conventional treatment	
Reporting group title	Group 1
Reporting group description: Autologous bone marrow mononucleated cells	
Reporting group title	Group 2
Reporting group description: Autologous bone marrow mononucleated cells	
Reporting group title	Group 3
Reporting group description: Autologous bone marrow mononucleated cells	

Primary: Degree of vasculogenesis

End point title	Degree of vasculogenesis[1]
End point description: The following data correspond to the transcutaneous oxygen pressure observed in both the control group and the treatment group 12 months after treatment.	
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: No statistical analyses for this end point

End point values	Group control	Group 1	Group 2	Group 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	10	9
Units: mmHg				
arithmetic mean (confidence interval 95%)	-5 (-27 to 17)	16 (9 to 23)	16 (9 to 23)	16 (9 to 23)

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 final report

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 March 2009	Inclusion of a new collaborating service from another center
19 May 2009	Amendment not relevant
29 October 2009	Amendment not relevant

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported