Clinical trial results:
Using Mesenchymal Stem Cells From Adipose Tissue (CeTMAd) as Cell Regeneration Therapy in Chronic Ischemic Syndrome of Lower Limbs in Diabetic Patients

Summary

EudraCT number	2008-001837-88
Trial protocol	ES
Global end of trial date	26 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 clínico CeTMAdlCPD2008_dic 2022(F).pdf)

Trial information

Trial identification

Sponsor protocol code	CeTMAd/ICPD/2008

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
Scientific contact	ROSARIO CARMEN MATA ALCÁZAR-CABALLERO, Fundación Pública Andaluza Progreso y Salud M.P., rosario.mata@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	26 December 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 December 2022
Global end of trial reached?	Yes
Global end of trial date	26 December 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy and safety of regenerative treatment with adipose tissue mesenchymal stem cells (CeTMAd), administered intra-arterially in diabetic patients with critical ischemia of at least one lower limb and without the possibility of revascularization or other therapeutic alternatives.
Complications derived from regenerative therapy and/or study procedures will be analyzed:
- The generation of new vessels (vasculogenesis) and the enhancement of collateral circulation (angiogenesis) will be studied.
- Complications derived from the procedure will be studied in the first 24h of CeTMAd administration, 1 month, 3 months, 6 months, 9 months and 12 months.

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	25 November 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 29
Worldwide total number of subjects	29
EEA total number of subjects	29

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)	11
From 65 to 84 years	18
85 years and over	0

Subject disposition

Recruitment
Recruitment details: -

Pre-assignment
Screening details: -

Pre-assignment period milestones	
Number of subjects started	29
Number of subjects completed	29

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 A
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	AUTOLOGOUS ADIPOSE TISSUE ADIPOSE TISSUE ADULT STEM MESENCHYMAL CELLS
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Intraarterial use
Dosage and administration details: 0,5 X 10^6 CÉLULAS/KG	
Arm title	Group B
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	AUTOLOGOUS ADIPOSE TISSUE ADIPOSE TISSUE ADULT STEM MESENCHYMAL CELLS
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Intraarterial use
Dosage and administration details: 10 X 10^6 CÉLULAS/KG	
Arm title	Group control
Arm description: -	
Arm type	Usual clinical practice
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Group A	Group B	Group control
Started	10	10	9
Completed	10	10	9

Baseline characteristics

Reporting groups	
Reporting group title	Group A
Reporting group description: -	
Reporting group title	Group B
Reporting group description: -	
Reporting group title	Group control
Reporting group description: -	

Reporting group values	Group A	Group B	Group control
Number of subjects	10	10	9
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	10	10	9
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	66.5	66.5	66.6
standard deviation	± 9.3	± 9.3	± 14.8
Gender categorical Units: Subjects			
Female	5	6	4
Male	5	4	5
Age categorical Units: Subjects			
Adults (18-64 years)	10	10	9
From 65-84 years	0	0	0
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	10	10	9
85 years and over	0	0	0

Safety			
Units: units			
arithmetic mean	65.5	66.5	66.6
standard deviation	± 9.3	± 9.3	± 14.8

Reporting group values	Total		
Number of subjects	29		
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)	29		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	15		
Male	14		
Age categorical			
Units: Subjects			
Adults (18-64 years)	29		
From 65-84 years	0		
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	29		
85 years and over	0		
Safety			
Units: units			
arithmetic mean			
standard deviation	-		

Subject analysis sets	
Subject analysis set title	Feasibility and safety
Subject analysis set type	Safety analysis

Subject analysis set description:

Assess the safety and feasibility of treatment regenerative with mesenchymal stem cells of adipose tissue administered intra-arterially in Diabetic patients with critical chronic ischemia of lower limbs and without the possibility of revascularization or other therapeutic alternatives.

Reporting group values	Feasibility and safety		
Number of subjects	29		
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)	9		
From 65-84 years	20		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	65,8		
standard deviation	±		
Gender categorical			
Units: Subjects			
Female	4		
Male	25		
Age categorical			
Units: Subjects			
Adults (18-64 years)	20		
From 65-84 years	9		
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)	20		
From 65-84 years	9		
85 years and over	0		
Safety			
Units: units			
arithmetic mean	65,8		
standard deviation	± 11		

End points

End points reporting groups

Reporting group title	Group A
Reporting group description: -	
Reporting group title	Group B
Reporting group description: -	
Reporting group title	Group control
Reporting group description: -	
Subject analysis set title	Feasibility and safety
Subject analysis set type	Safety analysis

Subject analysis set description:

Assess the safety and feasibility of treatment regenerative with mesenchymal stem cells of adipose tissue administered intra-arterially in Diabetic patients with critical chronic ischemia of lower limbs and without the possibility of revascularization or other therapeutic alternatives.

Primary: Safety

End point title	Safety[1]

End point description:

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 A	Group B	Group control	Feasibility and safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	10	10	9	
Units: units	10	10	9	9

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
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

Reporting groups	
Reporting group title	Group control

Reporting group description: -

Serious adverse events	Group control		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Group control		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 10 (50.00%)		
Renal and urinary disorders			
urinary infection			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	5		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 May 2010	Some of the exclusion criteria have been modified.
10 January 2011	The total number of patients to be recruited is modified
20 April 2012	Ophthalmoscopy is therefore eliminated as a Test of the Trial

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported