Clinical trial results:
A MULTICENTER PHASE I/II, OPEN, RANDOMIZED, RANDOMIZED CLINICAL TRIAL TO STUDY THE USE OF MESENCHYMAL STEM CELLS DERIVED FROM ADIPOSE TISSUE (CeTMAd) AS A CELL REGENERATION THERAPY FOR CRITICAL LOWER LIMB CRITICAL ISCHEMIA SYNDROME IN NON-DIABETIC PATIENTS.

Summary

EudraCT number	2009-013554-32
Trial protocol	ES
Global end of trial date	13 December 2018

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_CeTMAd_ICC_2009_dic 2022(F).pdf)

Trial information

Trial identification

Sponsor protocol code	CeTMAd/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
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	23 January 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 December 2018
Global end of trial reached?	Yes
Global end of trial date	13 December 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- Seguridad: Se estudiarán las posibles complicaciones derivadas del procedimiento en las primeras 24h de la administración de las CeTMAd, 1 mes, 3 meses, 6 meses, 9 meses y 12 meses.
- Factibilidad: Se estudiará la generación de nuevos vasos (vasculogénesis) y la potenciación de la circulación colateral (angiogénesis/ arteriogénesis).

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	10 January 2011
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: 31
Worldwide total number of subjects	31
EEA total number of subjects	31

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)	28
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	31
Number of subjects completed	31

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:

Expanded autologous adipose tissue adult mesenchymal stem cells

Arm type	Experimental
Investigational medicinal product name	Expanded autologous adipose tissue adult mesenchymal stem cells
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intraarterial use

Dosage and administration details:

0,5 x 10e6 cells/kg patient

Arm title	Group 2

Arm description:

Expanded autologous adipose tissue adult mesenchymal stem cells

Arm type	Experimental
Investigational medicinal product name	Expanded autologous adipose tissue adult mesenchymal stem cells
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intraarterial use

Dosage and administration details:

1 x 10e6 cells/kg patient

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:

Not apply

Number of subjects in period 1	Group 1	Group 2	Group control
Started	11	10	10
Completed	11	10	10

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group 1
Reporting group description:	
Expanded autologous adipose tissue adult mesenchymal stem cells	
Reporting group title	Group 2
Reporting group description:	
Expanded autologous adipose tissue adult mesenchymal stem cells	
Reporting group title	Group control
Reporting group description:	
Conventional treatment	

Primary: Evaluate the safety and feasibility of treatment

End point title	Evaluate the safety and feasibility of treatment[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 1	Group 2	Group control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	10	10	
Units: units	11	10	10	

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
17 June 2010	One of the exclusion criteria was narrowed better and one of the inclusion criteria was expanded among other changes.
11 January 2011	The main modification in the protocol of this clinical trial consists of the elimination of one of the treatment arms specified in said protocol. Specifically, it is about the removal of the 2 x 106 treatment branch cells/kg patient. Which leads to your time, to a decrease in the number of patients to recruit from 48 to 30 patients evaluable in total.
20 April 2012	The main modification in the protocol of this clinical trial consists of the expansion of the recruitment period.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported