Clinical trial results:
Phase I / II, multicenter, double blind, randomized, comparison of two groups and two doses, to evaluate the safety and efficacy of autologous ASCs in the treatment of fecal incontinence.

Summary

EudraCT number	2010-021659-17
Trial protocol	ES
Global end of trial date	29 September 2017

Results information

Result version number	v1 (current)
This version publication date	29 November 2023
First version publication date	29 November 2023
Summary attachment (see zip file)	Final Report_Summary (Resumen Informe final EC CMMAd_InFe_2011DEF(F).pdf)

Trial information

Trial identification

Sponsor protocol code	CMMAd/InFe/2011

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 ALCAZAR-CABALLERO, Fundación Pública Andaluza Progreso y Salud M.P., rosario.mata@juntadeandalucia.es
Scientific contact	ROSARIO CARMEN MATA ALCAZAR-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	13 August 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 September 2017
Global end of trial reached?	Yes
Global end of trial date	29 September 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and feasibility of therapy with autologous mesenchymal stem cells from adipose tissue in the treatment of fecal incontinence.

Protection of trial subjects:

All patients have the right to discontinue the study at any time and may be withdrawn from the study for any reason of benefit to their well-being. On the other hand, in accordance with good clinical practice, those patients who have abandoned the study prematurely will have been recommended another alternative and, in the event that the cause has been a significant Adverse Event, the patients have been controlled by the investigator until appropriate termination, that is, until the adverse event has disappeared or until it has been determined to be permanent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 September 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	24 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	10

From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

During the recruitment phase, which lasted 12 months, a total of 18 participating subjects were included. These patients were randomly assigned to one of the intervention groups (8 patients in the CMMAd group / 10 patients in the placebo group).

Pre-assignment

Screening details:

A unique internal sphincter defect and/or external, at any level of the anal canal, of any cause.
Severity of faecal incontinence of 12 or more in the Wexner Score and/or at least six episodes of faecal incontinence for a period of 28 days.
Duration of faecal incontinence of at least two years prior to inclusion.

Period 1

Period 1 title	Recruitment and follow-up (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A

Arm description:

Autologous mesenchymal stem cell suspension from adipose tissue (CMMAd) in a dose of 40 million, administered by intralesional injection.

Arm type	Experimental
Investigational medicinal product name	Autologous mesenchymal stem cells from adipose tissue (CMMAd)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intralesional use

Dosage and administration details:

40x10E6 CMMAd

Arm title	Group B (control)

Arm description:

Placebo (Lactated Ringer's solution)

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intralesional use

Dosage and administration details:

Placebo

Number of subjects in period 1	Group A	Group B (control)
Started	8	8
Completed	8	8

Baseline characteristics

Reporting groups	
Reporting group title	Group A
Reporting group description:	
Autologous mesenchymal stem cell suspension from adipose tissue (CMMAd) in a dose of 40 million, administered by intralesional injection.	
Reporting group title	Group B (control)
Reporting group description:	
Placebo (Lactated Ringer's solution)	

Reporting group values	Group A	Group B (control)	Total
Number of subjects	8	8	16
Age categorical			
Units: Subjects			
Adults (18-64 years)	8	8	16
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
From 65-84 years	0	0	0
85 years and over	0	0	0
Not recorded	0	0	0
Age continuous			
Units: years			
median	63.38	48.90	
full range (min-max)	44 to 75	33 to 78	-
Gender categorical			
Units: Subjects			
Female	6	5	11
Male	2	3	5
Female and male			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants	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)	8	8	16
From 65-84 years	0	0	0
85 years and over	0	0	0
Not recorded	0	0	0

Faecal Incontinence			
Units: subjects			
median	63.38	48.90	
full range (min-max)	44 to 75	33 to 78	-

Subject analysis sets

Subject analysis set title	Feasibility and safety
Subject analysis set type	Full analysis

Subject analysis set description:

Feasibility and safety

Reporting group values	Feasibility and safety		
Number of subjects	16		
Age categorical			
Units: Subjects			
Adults (18-64 years)	16		
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		
From 65-84 years	0		
85 years and over	0		
Not recorded	0		
Age continuous			
Units: years			
median			
full range (min-max)			
Gender categorical			
Units: Subjects			
Female	12		
Male	4		
Female and male			
Units: Subjects			
In utero	0		
Preterm newborn infants	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)	16		
From 65-84 years	0		
85 years and over	0		
Not recorded	0		
Faecal Incontinence			
Units: subjects			
median			

full range (min-max)			

End points

End points reporting groups

Reporting group title	Group A
Reporting group description:	
Autologous mesenchymal stem cell suspension from adipose tissue (CMMAd) in a dose of 40 million, administered by intralesional injection.	
Reporting group title	Group B (control)
Reporting group description:	
Placebo (Lactated Ringer's solution)	
Subject analysis set title	Feasibility and safety
Subject analysis set type	Full analysis
Subject analysis set description:	
Feasibility and safety	

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 (control)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	8		
Units: units	8	8		

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	Hip fracture
Reporting group description: -	
Reporting group title	Gastrointestinal disorders
Reporting group description: -	
Reporting group title	Post-procedure hematoma
Reporting group description: -	

Serious adverse events	Hip fracture	Gastrointestinal disorders	Post-procedure hematoma
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Post-procedure hematoma			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal disorders			
subjects affected / exposed	1 / 10 (10.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Hip fracture	Gastrointestinal disorders	Post-procedure hematoma
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Post-procedure hematoma			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Gastrointestinal disorders			
subjects affected / exposed	0 / 10 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 September 2013	This amendment comes from mainly brought about by the modification and/or clarification of certain inclusion criteria, and exclusion criteria, given that by experience cumulative of the research team since the final version was produced of the protocol is considered appropriate Update these criteria
24 March 2014	New centers are added

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported