



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) | | | |
|----------------------|--|--|--|

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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 occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 8 (12.50%) 0 | 0 / 10 (0.00%) 0 |
| Blood and lymphatic system disorders Post-procedure hematoma subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 8 (12.50%) 0 | 0 / 10 (0.00%) 0 |
| Gastrointestinal disorders Gastrointestinal disorders subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 8 (12.50%) 0 | 0 / 10 (0.00%) 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