Clinical trial results:
Clinical Trial Phase II Multicenter Open Randomized Trial of the Therapeutic Use of Cells Intraportal Infusion of Autologous Bone Marrow Mononuclear as Enhancing Liver Regeneration Prior to Performing Extended Hepatic Resection.

Summary

EudraCT number	2009-017793-20
Trial protocol	ES
Global end of trial date	20 May 2015

Results information

Result version number	v1 (current)
This version publication date	01 December 2023
First version publication date	01 December 2023
Summary attachment (see zip file)	Final Report_summary (Resumen Informe final CMMo_RH_2009 DIC 21 Def.docx(F).pdf)

Trial information

Trial identification

Sponsor protocol code	CMMo/RH/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., +34 955 048 366, terapias.avanzadas@juntadeandalucia.es
Scientific contact	Rosario Carmen Mata Alcázar-Caballero , Fundación Pública Andaluza Progreso y Salud M.P., +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	01 December 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 May 2015
Global end of trial reached?	Yes
Global end of trial date	20 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the feasibility and safety of autologous bone narrow mononuclear cells as enhancer of hepetic regeneration

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All patients have the right to discontinue the study at any time and may be withdrawn from the study for any reason of benefit to their well-being.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 March 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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)	13
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

14 patients were included (after signing the consent) being one a selection fault and, consequently, 13 measurable patients according to the definition of population by intention of being treated. These patients were randomly assigned to one of the intervention groups (6 patients in group 1 (study) / 7 patients in group 2 (control).

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	13
Number of subjects completed	13

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:

Study group (CMMo)

Arm type	Experimental
Investigational medicinal product name	CMMo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intraportal use

Dosage and administration details:

A single dose of bone marrow mononucleated cells (10 ml)

Arm title	Group 2

Arm description:

Control

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Group 1	Group 2
Started	6	7
Completed	6	7

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group 1
Reporting group description: Study group (CMMo)	
Reporting group title	Group 2
Reporting group description: Control	
Subject analysis set title	Feasibility and safety
Subject analysis set type	Full analysis
Subject analysis set description: Feasibility and safety	

Primary: Feasibility

End point title	Feasibility[1]
End point description:	
End point type	Primary
End point timeframe: From the inclusion of the first patient to the last visit of the last patient	

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		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: units	6	7		

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	Haemorrhagic shock
Reporting group description: -	
Reporting group title	Subphrenic collection
Reporting group description: -	
Reporting group title	Pulmonary thromboembolism
Reporting group description: -	
Reporting group title	Bradycardia
Reporting group description: -	
Reporting group title	Fever
Reporting group description: -	
Reporting group title	Intra-abdominal biliary
Reporting group description: -	
Reporting group title	Persistence of biliary collection
Reporting group description: -	

Serious adverse events	Haemorrhagic shock	Subphrenic collection	Pulmonary thromboembolism
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Bradycardia	Fever	Intra-abdominal biliary
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Persistence of biliary collection		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)		

number of deaths (all causes) number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Haemorrhagic shock	Subphrenic collection	Pulmonary thromboembolism
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 6 (16.67%)
Cardiac disorders Bradycardia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0
Blood and lymphatic system disorders Haemorrhagic shock subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0
Respiratory, thoracic and mediastinal disorders Pulmonary tromboembolism subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0
Hepatobiliary disorders Intra-abdominal biliary subjects affected / exposed occurrences (all) Persistence of biliary collection subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 0 1 / 6 (16.67%) 0	1 / 6 (16.67%) 0 1 / 6 (16.67%) 0	1 / 6 (16.67%) 0 1 / 6 (16.67%) 0
Renal and urinary disorders Subphrenic collection subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0
Infections and infestations Fever subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0	1 / 6 (16.67%) 0

Non-serious adverse events	Bradycardia	Fever	Intra-abdominal biliary
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 7 (14.29%)
Cardiac disorders			
Bradycardia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Haemorrhagic shock			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Pulmonary tromboembolism			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Intra-abdominal biliary			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	0	0
Persistence of biliary collection			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Subphrenic collection			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	0	0
Infections and infestations			
Fever			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	0	0

Non-serious adverse events	Persistence of biliary collection		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 7 (14.29%)		
Cardiac disorders			
Bradycardia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	0		

Blood and lymphatic system disorders Haemorrhagic shock subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 0		
Respiratory, thoracic and mediastinal disorders Pulmonary tromboembolism subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 0		
Hepatobiliary disorders Intra-abdominal biliary subjects affected / exposed occurrences (all) Persistence of biliary collection subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 0 1 / 7 (14.29%) 0		
Renal and urinary disorders Subphrenic collection subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 0		
Infections and infestations Fever subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 December 2009	Investigational therapy and stem cell application procedure
30 January 2011	New centres have been included and some exclusion criteria have been modified
10 October 2011	Some inclusion and exclusion criteria have been modified. Some centers are also added

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported