



Clinical trial results:

Clinical trial Phase I/II, test of concept, double blind, randomized, controlled with placebo, to evaluate the safety and efficiency of the treatment with expanded adult mesenchymal stem cells from allogenic adipose tissue, in patients with HIV infection with controlled viral load and immunological discordant response.

Summary

EudraCT number	2014-000307-26
Trial protocol	ES
Global end of trial date	30 July 2019

Results information

Result version number	v1 (current)
This version publication date	14 February 2024
First version publication date	14 February 2024
Summary attachment (see zip file)	CeTMAd-VIH-2014 (CeTMAd_VIH_2014_Sinopsis Resultados_Def(F).pdf) CeTMAd-VIH-2014 (CeTMAd-VIH-201_Informe Clínico Final_DEF_compressed.pdf)

Trial information

Trial identification

Sponsor protocol code	CeTMAd-VIH-2014
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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, Sevilla, Spain,
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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	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 July 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 June 2019
Global end of trial reached?	Yes
Global end of trial date	30 July 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. To evaluate the safety of the intravenous infusion of 4 doses of allogenic mesenchimal stem cells from adipose tissue (ASC), in patients with infection for HIV and immunological discordant response.
2. To evaluate the efficiency of the intravenous infusion of 4 ASC's doses in the immunological recovery after 3 monthly cycles of CeTMAd's infusion and 1 additional infusion in week 20 in patients with infection for HIV and immunological discordant response.

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	01 June 2016
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: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	5
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	5
Number of subjects completed	5

Period 1

Period 1 title	Recruitment and follow-up (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Group A
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	CeTMAd
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intraarterial use

Dosage and administration details:

0.5x10⁶ células / kg peso paciente.

Number of subjects in period 1	Group A
Started	5
Completed	5

Baseline characteristics

Reporting groups

Reporting group title	Group A
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Reporting group description: -

Reporting group values	Group A	Total	
Number of subjects	5	5	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	5	5	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	5	5	

End points

End points reporting groups

Reporting group title	Group A
Reporting group description: -	
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: Information included in summary

End point values	Group A	Feasibility and safety		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	5		
Units: units	5	5		

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
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Dictionary used

Dictionary name	MedDRA
Dictionary version	NA

Reporting groups

Reporting group title	Group 1
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Reporting group description: -

Serious adverse events	Group 1		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Group 1		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)		
Vascular disorders			
venous thrombosis			
subjects affected / exposed	5 / 5 (100.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 September 2016	The use of premedication is considered before each CetMAd infusion. Update of co-investigators and inclusion of the UPCIT of the CHUGr as the center involved in the trial. Update of the scale for the gradation of AAs (DAIDs table), of the clinical trial schedule repealed regulations (EECC, donation of tissues and TAs), and of the methods accepted contraceptives.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported