Clinical trial results:
Multicenter clinical trial to evaluate the safety and feasibility of allogeneic tissue engineered product (human nanostructured artificial cornea) in patients with advanced corneal trophic ulcers refractory to (ophtalmic) conventional treatment.

Summary

EudraCT number	2010-024290-40
Trial protocol	ES
Global end of trial date	15 September 2022

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 (CAH_Ulc_2010_Sinopsis Resultados_dic 2022 DEF_firma(F).pdf)

Trial information

Trial identification

Sponsor protocol code	CAH/Ulc/2010

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, ROSARIO CARMEN MATA ALCÁZAR-CABALLERO, rosario.mata@juntadeandalucia.es
Scientific contact	ROSARIO CARMEN MATA ALCÁZAR-CABALLERO, ROSARIO CARMEN MATA ALCÁZAR-CABALLERO, 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	10 January 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 September 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety, feasibility and evidence of clinical efficacy of a model of human artificial nanostructured lamellar corneal, in patients with severe corneal disease for which there is currently no effective therapeutic.

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	03 September 2012
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: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	15

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	15
Number of subjects completed	15

Period 1

Period 1 title	Safety and feasibility (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: -

Arm type	Experimental
Investigational medicinal product name	Artificial cornea
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Implant
Routes of administration	Ocular use

Dosage and administration details:

Not apply

Arm title	Group control

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Amniotic membrane transplant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Matrix for implantation matrix
Routes of administration	Ocular use

Dosage and administration details:

Not apply

Number of subjects in period 1	Group 1	Group control
Started	10	5
Completed	10	5

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group 1
Reporting group description: -	
Reporting group title	Group control
Reporting group description: -	

Primary: Safety and feasibility

End point title	Safety and feasibility[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: It is detailed in the summary of the final clinical report

End point values	Group 1	Group control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	5		
Units: units	10	5		

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 final clinical report

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 August 2013	Monitor change
29 November 2013	The calendar and expected completion date are updated
05 March 2014	The change of the person designated as Principal Investigator at the Hospital is communicated San Cecilio University of Granada
02 February 2016	New participating centers are added
27 December 2016	Inclusion criteria are modified
27 March 2018	For better management of services and development of tasks related to the clinical trial, various changes are made to the equipment researchers from the participating centers
02 May 2019	The main researcher at the Reina Sofia University Hospital changes
10 September 2021	The principal investigator of the Costa del Sol hospital changes
24 March 2022	The person designated as Coordinating Investigator of the study is modified

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported