Clinical trial results:
ESTUDIO PARA EVALUAR LA EFICACIA Y SEGURIDAD DE LA LENALIDOMIDA EN EL TRATAMIENTO DEL LUPUS ERITEMATOSO CUTÁNEO.
STUDY TO EVALUATE THE EFFECTIVENESS AND SAFETY OF LENALIDOMIDE IN THE TREATMENT OF CUTANEOUS LUPUS ERYTHEMATOSUS.

Summary

EudraCT number	2009-016508-21
Trial protocol	ES
Global end of trial date	31 October 2010

Results information

Result version number	v1 (current)
This version publication date	07 November 2021
First version publication date	07 November 2021

Trial information

Trial identification

Sponsor protocol code	ORDI-02

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01408199
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	VHIR
Sponsor organisation address	Passeig Vall Hebron 119-129, Barcelona, Spain, 08035
Public contact	Joaquin Lopez-Soriano, VHIR, joaquin.lopez.soriano@vhir.org
Scientific contact	Josefina Cortés, VHIR, fina.cortes@vhir.org

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	31 October 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy and safety of lenalidomide in patients with refractory Cutaneous lupus erythematosus

Protection of trial subjects:

For all patients, there was no known hypersensitivity to thalidomide. Women were excluded from the study if pregnant, lactating or not using adequate contraception

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 January 2009
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:

All patients were female and of Caucasian origin, with refractory cutaneous lupus disease, histological proven CLE with or without associated systemic lupus erythematosus (SLE) disease diagnosed according to the American College of Rheumatology (ACR) SLE classification criteria; presence of at least a grade II erythema; stable prednisone

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Lenalidomide
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Lenalidomide was started at 5 mg/day for 4 weeks. At that time, if no clinical improvement was observed, using the criteria specified before, dose was increased to 10 mg/day. Otherwise, lenalidomide was sustained at 5 mg/day in case of partial response or decreased progressively monthly until its withdrawal if complete response was achieved.

Number of subjects in period 1	Lenalidomide
Started	15
Completed	15

Baseline characteristics

End points

End points reporting groups

Reporting group title	Lenalidomide

Reporting group description: -

Primary: Patients achieving complete response

End point title	Patients achieving complete response[1]

End point description:

The efficacy primary endpoint was the proportion of patients achieving complete response. Clinical response was evaluated by the validated Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI). Response was defined as follows: complete response (CR) as a complete resolution of the inflammatory rash (CLASI activity score = 0); partial response (PR) by at least a 50% improvement in the CLASI score by week 12 when compared to baseline, and no response when no improvement or worsening in the CLASI score was observed at the same time period

End point type	Primary

End point timeframe:

12 weeks

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 statistics is given since no comparison with any group is done (single arm)

End point values	Lenalidomide			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: percent				
number (not applicable)	12			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 12 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups	
Reporting group title	Total adverse events

Reporting group description: -

Serious adverse events	Total adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Total adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 15 (13.33%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Gastrointestinal disorders			

Vomiting subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1 1 / 15 (6.67%) 1		
Metabolism and nutrition disorders Weight decreased subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The main limitation is the absence of a randomized group control and the insufficient small sample size to draw conclusions at the histological subtype level since the majority of included patients had DLE. Further larger trials are required

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/23217273