Clinical trial results:
Randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of cyclosporine mucoadhesive gel at two different concentrations in the topical treatment of lichen planus in the oral mucosa.

Summary

EudraCT number	2017-000791-29
Trial protocol	ES
Global end of trial date	08 October 2018

Results information

Result version number	v1 (current)
This version publication date	11 November 2021
First version publication date	11 November 2021
Summary attachment (see zip file)	Final report summary (Resumen informe final resultados CICLO-LPO_13-07-2020. FIRMADO.pdf)

Trial information

Trial identification

Sponsor protocol code	CICLO-LPO

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Clínica Universidad de Navarra
Sponsor organisation address	Avda. Pío XII, 36, Pamplona, Spain, 31008
Public contact	UCEC, Clínica Universidad de Navarra, 34 9482554002725, ucicec@unav.es
Scientific contact	UCEC, Clínica Universidad de Navarra, 34 9482554002725, ucicec@unav.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 August 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 October 2018
Global end of trial reached?	Yes
Global end of trial date	08 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of two different concentrations of cyclosporin A (0.5% and 2%) cyclosporin topical on a mucoadhesive gel in the topical treatment for 6 weeks of oral mucosa lichens.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 July 2017
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: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

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)	4
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

7 patients were included instead of the 28 evaluable patients indicated in the protocol, due to the shortage of study medication.

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer

Blinding implementation details:

The organoleptic characteristics of the preparations will be similar to avoid the blinding opening.
A single specialist (blinded for treatment) will assess the extent of the mucosa. A different specialist, also blind, by analyzing the photographs and coded images.

Arms

Arm title	Treatment

Arm description:

Each patient's kit will contain 2 x 25g aluminum tubes of study drug or placebo. Thus, each patient will receive 2 kits with two tubes each: a tube that will contain the drug under study (cyclosporine 2% or 0.5%) and another tube that will contain a placebo of the drug. Each patient's kit will be labeled and each kit will be dispensed on visits 1 and 4

Arm type	Experimental
Investigational medicinal product name	cyclosporine 2% or 0.5%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for cutaneous solution
Routes of administration	Cutaneous use

Dosage and administration details:

cyclosporine 2% or 0.5%

Number of subjects in period 1	Treatment
Started	7
Completed	7

Baseline characteristics

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description:

Each patient's kit will contain 2 x 25g aluminum tubes of study drug or placebo. Thus, each patient will receive 2 kits with two tubes each: a tube that will contain the drug under study (cyclosporine 2% or 0.5%) and another tube that will contain a placebo of the drug. Each patient's kit will be labeled and each kit will be dispensed on visits 1 and 4

Primary: efficacy of two different concentrations of cyclosporin

End point title	efficacy of two different concentrations of cyclosporin[1]

End point description:

A descriptive analysis will be carried out by calculating the frequencies and percentages for the qualitative variables, and the medians and ranges of the quantitative variables.

End point type	Primary

End point timeframe:

Evaluations will be performed by a specialist without knowing the type of treatment received at baseline visits, at weeks 2, 4 and 6.

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 analysis was added because the website does not allow to set the design of this study. Double blind Intraindividual randomized placebo controlled trial (each patient received both, placebo and treatment). Placebo and control areas was compared using the Wilcoxon test. Pre-specified P-value was 0.05 for statistical significance.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	7[2]			
Units: Percentage and frecuency	7			

Notes:

[2] - 7 patients were included instead of the 28 evaluable patients indicated in the protocol

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 1 year	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	20
Reporting groups	
Reporting group title	Treatment

Reporting group description: -

Serious adverse events	Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)		
Nervous system disorders			
Migraine headache			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
General disorders and administration site conditions			
Stinging			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Gastric reflux			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Headache			

subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1		
Gastrointestinal disorders inflammation of the gum subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 1		
Skin and subcutaneous tissue disorders Erosive lichen planus subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 1		
Musculoskeletal and connective tissue disorders Knee pain subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 1		
Infections and infestations DENTAL INFLAMMATION subjects affected / exposed occurrences (all) sinusitis subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 1 1 / 7 (14.29%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 August 2017	Protocol amendment

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
08 October 2018	Due to a shortage of medication, recruitment had to be stopped. Given the refusal of the manufacturer to provide more medication, we had to close the trial for this reason	-

Notes:

Limitations and caveats

None reported