Clinical trial results:
Biological standarization of Cupressus arizonica allergen extract to determine the biological activity in histamine equivalent units (HEP)

Summary

EudraCT number	2013-001309-98
Trial protocol	ES
Global end of trial date	24 December 2015

Results information

Result version number	v1 (current)
This version publication date	15 May 2022
First version publication date	15 May 2022
Summary attachment (see zip file)	Summary (CT 199 - CSR- Cupressus SUMMARY EUDRA.pdf)

Trial information

Trial identification

Sponsor protocol code	608-PR-PRI-199

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02512653
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Laboratorios LETI S.L.
Sponsor organisation address	c/Sol nº 5, Madrid, Spain, 28760
Public contact	Medical Department, LABORATORIOS LETI, S.L.Unipersonal, 34 917711790, clinicalresearch@leti.com
Scientific contact	Medical Department, LABORATORIOS LETI, S.L.Unipersonal, 34 917711790, clinicalresearch@leti.com

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	06 August 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 December 2015
Global end of trial reached?	Yes
Global end of trial date	24 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to assess the concentration of Cupressus arizonica allergen extract that elictis a wheal size equivalent to that of 10 mg/ml histamine dyhidrochloride solution.

Protection of trial subjects:

According to ICH-GCP, patients had to give their consent to participate in the clinical trial, only after having been fully informed by the investigator of the nature, significance and implications thereof.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 September 2015
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: 33
Worldwide total number of subjects	33
EEA total number of subjects	33

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)	33
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Clinical history of respiratory allergy (rhinitis and / or rhinoconjunctivitis and / or asthma) against Cupressus arizonica.

Period 1

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

Arms

Arm title	Experimental

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Allergen extract of Cupressus arizonica
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Subcutaneous use

Dosage and administration details:

1, 5, 10 and 15 mg/ml

Investigational medicinal product name	Histamine Diclorhidrate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Subcutaneous use

Dosage and administration details:

10mg/ml

Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Subcutaneous use

Dosage and administration details:

Not applicable

Number of subjects in period 1	Experimental
Started	33
Completed	20
Not completed	13
Protocol deviation	13

Baseline characteristics

End points

End points reporting groups

Reporting group title	Experimental

Reporting group description: -

Primary: Efficacy

End point title	Efficacy[1]

End point description:

End point type	Primary

End point timeframe:

The total duration of the study for a patient was approximately 30 minutes plus at least 30 minutes, under observation in the medical rooms, after the application of the Titrated Skin Prick test.

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: Statistical results were not relevant for publish

End point values	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Size	20			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

During the clinical trial, adverse events could be spontaneously reported or elicited during open- ended questioning, examination, or evaluation of the patient

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	nk

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

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: No adverse events were reported in the clinical trial.

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

None reported