Clinical trial results:
Biological standardization of Alternaria alternata allergen extract to determine the biological activity in histamine equivalent units (HEP).

Summary

EudraCT number	2013-001308-13
Trial protocol	ES
Global end of trial date	26 November 2014

Results information

Result version number	v1
This version publication date	15 May 2022
First version publication date	15 May 2022
Summary attachment (see zip file)	Synopsis Final Report (CT 198 - CSR_Synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	301-PR-PRI-198

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	LABORATORIOS LETI S.L.U
Sponsor organisation address	c/ SOL, TRES CANTOS, MADRID, Spain, 28760
Public contact	Departamento Médico, LABORATORIOS LETI S.L.U, +34 917711790, clinicalresearch@leti.com
Scientific contact	Departamento Médico, LABORATORIOS LETI S.L.U, +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	24 August 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 November 2014
Global end of trial reached?	Yes
Global end of trial date	26 November 2014
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 alternaria alternata allergen extract that elicits a wheal size equivalent to that of a 10 mg/ml histamine dyhidrochloride solution.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 February 2014
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: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

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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	Experimental

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Alternaria alternata allergen extract
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/skin-prick test
Routes of administration	Cutaneous use

Dosage and administration details:

Four ten-fold concentrations of Alternaria alternata allergen extract (10, 1, 0.1 and 0.01 mg/ml).

Number of subjects in period 1	Experimental
Started	30
Completed	26
Not completed	4
Consent withdrawn by subject	1
Protocol deviation	3

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	30	30	
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)	30	30	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	16	16	
Male	14	14	

End points

End points reporting groups

Reporting group title	Experimental

Reporting group description: -

Primary: The primary efficacy endpoint was the wheal size area (mm2) on the skin at the site of the puncture during the immediate phase

End point title	The primary efficacy endpoint was the wheal size area (mm2) on the skin at the site of the puncture during the immediate phase[1]

End point description:

End point type	Primary

End point timeframe:

The clinical trial consisted of 1 or 2 site visits per patient of approximately 30 minutes, depending on the possibility to assess eligibility criteria during visit 1.

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: The information regarding statistical analyses provide confidential information not available to be shared according to company disclosure.

End point values	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: mm2				
geometric mean (standard deviation)	4.02 (± 8.25)			

Attachments (see zip file)	CT 198 - CSR_Alternaria alternata_Final_Synopsis.pdf

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: One year 2014	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	5

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: No Adverse events were reported in this 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