



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	v2 (current)
This version publication date	15 December 2022
First version publication date	15 May 2022
Version creation reason	• Correction of full data set Request by EudraCT
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 dihydrochloride 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 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:

Clinical history of respiratory allergy (rhinitis and / or rhinoconjunctivitis and / or asthma) against *Alternaria alternata*.

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	<i>Alternaria alternata</i> allergen extract
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/skin-prick test
Routes of administration	Subcutaneous use

Dosage and administration details:

10, 1, 0.1, 0.01 mg/ml

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

Dosage and administration details:

Not applicable

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: 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	26			
Units: Logarithmic regression	26			

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	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: The study was cancelled and no statistical data was performed

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