



Clinical trial results:

Biological standardization of Chenopodium album allergen extract to determine the biological activity in HEP units.

Summary

EudraCT number	2012-001937-15
Trial protocol	ES
Global end of trial date	22 May 2014

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)	Synopsis (CSR Chenopodium album standarization-Summary_eudra.pdf)

Trial information

Trial identification

Sponsor protocol code	6062-PR-PRI-195
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01675349
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Laboratorios LETI S.L.U.
Sponsor organisation address	c/Sol nº 5, Madrid, Spain,
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	18 April 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 May 2014
Global end of trial reached?	Yes
Global end of trial date	22 May 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 Chenopodium album allergen extract that elicits a wheal size equivalent to that of a 10 mg/ml histamine dyhydrochloride solution.

Protection of trial subjects:

All subjects included consented to participate in the trial and signed the informed consent form. One copy was given to the patient and the original was kept on file at the research site.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 November 2012
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: 48
Worldwide total number of subjects	48
EEA total number of subjects	48

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)	48
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Clinical history positive to inhalation allergy (rhinitis and/or rhinoconjunctivitis and/or asthma) due to Chenopodium album

Period 1

Period 1 title	Baseline (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	Chenopodium album Prick test
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Subcutaneous use

Dosage and administration details:

0,2; 2 y 20 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	48
Completed	23
Not completed	25
Screening failure	16

Protocol deviation	9
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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
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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 analyses is not relevant for published purpose

End point values	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: mm2	23			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	NK
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Reporting groups

Reporting group title	Adverse Events
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Reporting group description: -

Serious adverse events	Adverse Events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 48 (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	Adverse Events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 48 (2.08%)		
Immune system disorders			
Local reaction			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences (all)	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

None reported