



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 dyhydrochloride 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:

SUBJECTS WITH RINOCONJUNTIVIS

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