



Clinical trial results:

OPEN CLINICAL TRIAL, MULTICENTER, WITH SUBCUTANEOUS IMMUNOTHERAPY IN DEPOT PRESENTATION, IN PATIENTS WITH ALLERGY RHINOCONJUNCTIVITIS SENSITIZED TO PARIETARIA JUDAICA

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2014-001459-22 |
| Trial protocol | ES |
| Global end of trial date | 11 March 2016 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 02 July 2021 |
| First version publication date | 02 July 2021 |
| Summary attachment (see zip file) | Summary (BIA-PAR- DEPOT_ Resumen_20140311.pdf) |

Trial information

Trial identification

| | |
|-----------------------|---------------|
| Sponsor protocol code | BIA-PAR-DEPOT |
|-----------------------|---------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Roxall Medicina España S.A. |
| Sponsor organisation address | Parque Científico y Tecnológico de Bizkaia Edificio 401, Zamudio, Spain, 48170 |
| Public contact | Clinical Project Manager, Roxall Medicina España S.A., +34 94443 80 00, Maricruz.gomez@roxall.es |
| Scientific contact | Clinical Project Manager, Roxall Medicina España S.A., +34 94443 80 00, Maricruz.gomez@roxall.es |

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 | 11 March 2016 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 11 March 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 11 March 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of subcutaneous immunotherapy in depot presentation and guideline fast in patients with rhinoconjunctivitis with or without asthma sensitized to *Parietaria judaica*, aged between 18 and 60 through the identification and classification of adverse reactions throughout the duration of the clinical trial

Protection of trial subjects:

All patients were provided written informed consent prior to their participation after having received information related with the trial.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 01 September 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: 51 |
| Worldwide total number of subjects | 51 |
| EEA total number of subjects | 51 |

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) | 51 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

2 months of prerecruitment

Pre-assignment period milestones

| | |
|------------------------------|----|
| Number of subjects started | 51 |
| Number of subjects completed | 51 |

Period 1

| | |
|------------------------------|------------------------------|
| Period 1 title | Global clinical trial period |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Blinding implementation details:

Not applicable

Arms

| | |
|--|-------------------------------------|
| Arm title | Treatment arm |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | Allrgovac Parietaria Depot |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

1000 treatment units/ml

| Number of subjects in period 1 | Treatment arm |
|--------------------------------|---------------|
| Started | 51 |
| Completed | 51 |

Period 2

| | |
|----------------------------------|------------------------------|
| Period 2 title | Global clinical trial period |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |
| Blinding implementation details: | |
| Not applicable | |

Arms

| | |
|--|-------------------------------------|
| Arm title | Treatment arm |
| Arm description: | |
| Treatment with Parietaria Judaica. | |
| Arm type | active |
| Investigational medicinal product name | Allrgovac Parietaria Depot |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for solution for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| 1000 treatment units/ml | |

| | |
|---------------------------------------|---------------|
| Number of subjects in period 2 | Treatment arm |
| Started | 51 |
| Completed | 51 |

Baseline characteristics

End points

End points reporting groups

| | |
|--|---------------|
| Reporting group title | Treatment arm |
| Reporting group description: - | |
| Reporting group title | Treatment arm |
| Reporting group description: Treatment with Parietaria Judaica. | |

Primary: Number and percentage of adverse reactions

| | |
|---|--|
| End point title | Number and percentage of adverse reactions |
| End point description: | |
| End point type | Primary |
| End point timeframe: During 4 and a half months. | |

| End point values | Treatment arm | Treatment arm | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 51 | 51 | | |
| Units: Percentage | 51 | 51 | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Tolerability and safety statistical analysis |
| Statistical analysis description: Descriptive and efficacy statistical analyses were performed using the intention-to-treat (ITT) population (patients who met all inclusion/exclusion criteria, received at least one dose of treatment and had available data on efficacy variables) and the per-protocol population (patients who met previous criteria and moreover achieved their target maintenance dose and completed the study without any major protocol deviations). The differences between gender groups for demographic parameters in | |
| Comparison groups | Treatment arm v Treatment arm |
| Number of subjects included in analysis | 102 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[1] |
| P-value | < 0.0001 |
| Method | Wilcoxon (Mann-Whitney) |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 3886 |

| | |
|----------------------|--------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 100 |
| upper limit | 6000 |
| Variability estimate | Standard deviation |

Notes:

[1] - Descriptive analysis

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During 4 and a half months.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 2014 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------------------------|
| Reporting group title | Non serious adverse events |
|-----------------------|----------------------------|

Reporting group description: -

| Serious adverse events | Non serious adverse events | | |
|---|----------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

Frequency threshold for reporting non-serious adverse events: 3.8 %

| Non-serious adverse events | Non serious adverse events | | |
|---|----------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 51 (9.80%) | | |
| Skin and subcutaneous tissue disorders | | | |
| Urticaria | | | |
| subjects affected / exposed | 5 / 51 (9.80%) | | |
| occurrences (all) | 5 | | |

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