



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