Clinical trial results:
A multicentre, open label, phase IIb clinical trial to evaluate safety, tolerability and efficacy of the depigmented modified allergen extract of two mites mixes at 200 DPP/ml (DP/MG/14-1 Dermatophagoides pteronyssinus / Lepidoglyphus destructor and DP/MG/14-2 Dermatophagoides pteronyssinus /Blomia tropicalis) in subjects with allergic rhinitis or rhinoconjunctivitis, with controlled allergic asthma.

Summary

EudraCT number	2014-000172-26
Trial protocol	ES
Global end of trial date	09 May 2018
Results information	
Result version number	v2 (current)
This version publication date	08 July 2022
First version publication date	12 September 2021
Version creation reason	• Correction of full data set • Changes to summary attachments The trial information has a mistake. This trial has not been finalised prematurely.
Summary attachment (see zip file)	Synopsis Final Report (Synopsis_CSR_LETI_1301-PG-PSC-203_v1.0_2021MAY31_final_eng.pdf)

Trial information

Trial identification	
Sponsor protocol code	1301-PG-PSC-203
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02340130
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	LETI Pharma S.L.U.
Sponsor organisation address	c/Sol nº 5, Madrid, Spain, 28760
Public contact	Medical Department, LETI Pharma S.L.U, +34 917711790, clinicalresearch@leti.com
Scientific contact	Medical Department, LETI Pharma 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	31 May 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 May 2018
Global end of trial reached?	Yes
Global end of trial date	09 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this clinical trial is to evaluate the safety and tolerability of two allergens extract of mites mixes at 200 DPP/ml (DP/MG/14-1 Dermatophagoides pteronyssinus / Blomia tropicalis and DP/MG/14-2 Dermatophagoides pteronyssinus / Lepidoglyphus destructor) administered, using a rush build-up phase in subjects with allergic rhinitis or rhinoconjunctivitis, with controlled asthma.

Protection of trial subjects:

The investigator requested the voluntary informed consent to he participants, after ensuring that study candidates have had understood what their participation in the study.
The investigator was responsible for informing study candidates about the study characteristics, nature, purpose, procedures, estimated duration, and potential risks and benefits associated with their participation, clearly explaining to them what their participation involved.
The investigator answered any questions that may have arisen and explained to the study candidates that their participation was voluntary.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	22 September 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	40
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

It was planned to include 34 subjects in each treatment group, and perform an interim safety analysis of the first 18 subjects. It was not possible because they were included only 7 subjects at one of the treatment group.

Pre-assignment

Screening details:

They were selected for screening 43 subjects.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	DP/MG/14-1

Arm description:

D. pteronyssinus / B. tropicalis

Arm type	Experimental
Investigational medicinal product name	D. pteronyssinus / B. tropicalis
Investigational medicinal product code	• DP/MG/14-1
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

100/1000 DPP/ml, administering 0,5ml every 4-6 weeks

Arm title	DP/MG/14-2

Arm description:

D. pteronyssinus / L. destructor

Arm type	Experimental
Investigational medicinal product name	D. pteronyssinus / L. destructor
Investigational medicinal product code	DP/MG/14-2
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dose 100/100 DPP/ml, administration 0,5ml every 4-6 weeks

Number of subjects in period 1	DP/MG/14-1	DP/MG/14-2
Started	7	33
Completed	0	31
Not completed	7	2
Other	1	-
Lost to follow-up	3	2
Lack of efficacy	3	-

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial
Reporting group description: Safety population	

Reporting group values	Overall trial	Total	
Number of subjects	40	40	
Age categorical Units: Subjects			
Adults (18-64 years)	40	40	
Gender categorical Units: Subjects			
Female	26	26	
Male	14	14	

End points

End points reporting groups	
Reporting group title	DP/MG/14-1
Reporting group description: D. pteronyssinus / B. tropicalis	
Reporting group title	DP/MG/14-2
Reporting group description: D. pteronyssinus / L. destructor	

Primary: Safety	
End point title	Safety
End point description: Number of subjects (%) who experience at least one systemic reaction	
End point type	Primary
End point timeframe: Study Safety Period	

End point values	DP/MG/14-1	DP/MG/14-2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	33		
Units: Subjects	1	5		

Statistical analyses

Statistical analysis title	Safety evaluation, systemic reactions
Statistical analysis description: Subjects with immediate or delayed grade 2 or above systemic reaction	
Comparison groups	DP/MG/14-1 v DP/MG/14-2
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

2 years treatment

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	Safety population

Reporting group description: -

Serious adverse events	Safety population		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 40 (10.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Thrombophlebitis			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			

subjects affected / exposed	2 / 40 (5.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Asthma crisis			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchospasm			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	Safety population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 40 (40.00%)		
Nervous system disorders			
Headache			
subjects affected / exposed	10 / 40 (25.00%)		
occurrences (all)	18		
Migraine			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	8 / 40 (20.00%)		
occurrences (all)	8		
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	7 / 40 (17.50%)		
occurrences (all)	7		
Skin reaction			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		

Urticaria			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	4		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	14 / 40 (35.00%)		
occurrences (all)	14		
Influenza			
subjects affected / exposed	11 / 40 (27.50%)		
occurrences (all)	11		
Tooth infection			
subjects affected / exposed	6 / 40 (15.00%)		
occurrences (all)	6		
Pharyngitis			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	5		
Respiratory tract infection			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	5		
Nasopharyngitis			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 February 2016	Initial study design was modified to use two different concentrations of B. tropicalis (100/1000 DPP/ml and 100/500 DPP/ml), instead of the initial concentration foreseen (200 DPP/mL). An interim analysis was included and the possibility to an increase of the number of subjects to be included.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
15 July 2015	Patient diagnosed of trombophlebitis . This case was considered by the investigator as a Serious Adverse Event ("Other important medical event"), "not related to the study medication". The subject was withdrawn from the study as a consequence of this SAE	-

Notes:

Limitations and caveats

None reported