Clinical trial results:
Dermatophagoides pteronyssinus and Dermatophagoides farinae allergen extract. Determination of the allergenic potency in vivo histamine equivalent units (HEP)

Summary

EudraCT number	2013-005394-45
Trial protocol	ES
Global end of trial date	07 August 2018

Results information

Result version number	v1 (current)
This version publication date	02 October 2021
First version publication date	02 October 2021
Summary attachment (see zip file)	Resumen Informe Final (Resumen IF2.pdf)

Trial information

Trial identification

Sponsor protocol code	MM09-STD-011

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	INMUNOTEK S.L
Sponsor organisation address	Punto Mobi, 5, Alcalá de Henares, Spain,
Public contact	Miguel Casanovas; Medical Director, Inmunotek, S.L., 34 912908942110, mcasanovas@inmunotek.com
Scientific contact	Miguel Casanovas; Medical Director, Inmunotek, S.L., 34 912908942110, mcasanovas@inmunotek.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	28 November 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 August 2018
Global end of trial reached?	Yes
Global end of trial date	07 August 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective is to evaluate the concentration of an allergenic mixture of mites extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae necessary to produce a papule size equivalent to the one produced by a 10 mg/mL solution of histamine dihydrochloride.

Protection of trial subjects:

All adverse events, whether observed by the researcher or reported by the subject, must be recorded in the corresponding section of the data collection notebook and evaluated by the researcher.
The minimum information that must be specified will be the description, severity, duration, temporal sequence, treatment administered, and method of detection of the adverse event.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	17 August 2015
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: 23
Worldwide total number of subjects	23
EEA total number of subjects	23

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)	23
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Positive clinical record of inhaled allergy (rhinitis / rhinoconjunctivitis / asthma) against Dermatophagoides pteronyssinus or Dermatophagoides farinae.
A positive prick-test (average of the papule ≥ 3 mm diameter) with an extract of the same allergen and / or the presence of specific IgE against the allergen.

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	PRICK TEST

Arm description:

All study products were prepared in aqueous solution diluent. The composition of this diluent was 0.9% (w/v) Sodium Chloride, 0.4% (w/v) phenol plus 50% (v/v) glycerol.

An allergen extract of Dermatophagoides farinae with a concentration of 400 µg/mL. Three dilutions of 40, 4 and 0,4 µg/mL were prepared from the allergen extract.

An allergen extract of Dermatophagoides pteronyssinus with a concentration of 300 µg/mL. Three dilutions of 30, 3 and 0,3 µg/mL were prepared from the allergen extract.

Histamine dihydrochloride concentrated at 10mg/mL and prepared in a glycerinated phenol saline solution.

A glycerinated phenol saline solution.

Arm type	Experimental
Investigational medicinal product name	Dermatophagoides farinae Concentration No. 1 = 400 µg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Cutaneous use

Dosage and administration details:

1 drop in duplicate on the forearm

Investigational medicinal product name	Dermatophagoides farinae Concentration No. 2 = 40 µg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Cutaneous use

Dosage and administration details:

1 drop in duplicate on the forearm

Investigational medicinal product name	Dermatophagoides farinae Concentration No. 3 = 4 µg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Cutaneous use

Dosage and administration details: 1 drop in duplicate on the forearm	
Investigational medicinal product name	Dermatophagoides pteronyssinus concentration No. 1 =300 µg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Cutaneous use
Dosage and administration details: 1 drop in duplicate on the forearm	
Investigational medicinal product name	Dermatophagoides pteronyssinus concentration No. 2 =30 µg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Cutaneous use
Dosage and administration details: 1 drop in duplicate on the forearm	
Investigational medicinal product name	Dermatophagoides pteronyssinus concentration No. 3 =3 µg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/skin-prick test
Routes of administration	Cutaneous use
Dosage and administration details: 1 drop in duplicate on the forearm	
Investigational medicinal product name	Histamine dichloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Cutaneous use
Dosage and administration details: 1 drop on the forearm	
Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Cutaneous use
Dosage and administration details: 1 drop on the forearm	

Number of subjects in period 1	PRICK TEST
Started	23
Completed	23

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	23	23	
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)	23	23	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
median	30		
standard deviation	± 6.4	-	
Gender categorical Units: Subjects			
Female	15	15	
Male	8	8	

End points

End points reporting groups

Reporting group title	PRICK TEST

Reporting group description:

All study products were prepared in aqueous solution diluent. The composition of this diluent was 0.9% (w/v) Sodium Chloride, 0.4% (w/v) phenol plus 50% (v/v) glycerol.

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Histamine dihydrochloride concentrated at 10mg/mL and prepared in a glycerinated phenol saline solution.

A glycerinated phenol saline solution.

Primary: Size of the wheal induced by each concentration

End point title	Size of the wheal induced by each concentration[1]

End point description:

The size of the wheal produced by each different concentration of the allergen extract and the controls through the prick test, to determine biological potency.
15 minutes after the application of each solution onto the skin, the contour of every wheal was encircled using the Prick-Film® System.

End point type	Primary

End point timeframe:

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 calcule of the geometric mean of the two wheals produced by each allergen concentration (mm2) in relation with the positive (Histamine 10 mg/mL) and negative control (diluent's solution).
A linear regression analysis using the method of least squares was performed computing the constant a and b for each patient.
The calcule of the individual bioequivalent dose of each allergenic extract to achieve a wheal the same size as the positive control (individual 10 HEP) was performed.

End point values	PRICK TEST			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: mm2				
number (not applicable)	23			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
No adverse events during the reporting period	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.0

Frequency threshold for reporting non-serious adverse events: 0 %

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 occurred during the 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