Clinical trial results:
Juniperus oxycedrus and Cupressus arizonica allergen extracts. Determination of the in vivo allergenic potency in histamine equivalent units (HEP).

Summary

EudraCT number	2020-005389-32
Trial protocol	ES
Global end of trial date	05 February 2024

Results information

Result version number	v1 (current)
This version publication date	26 October 2025
First version publication date	26 October 2025

Trial information

Trial identification

Sponsor protocol code	T521-STD-044

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, 28805
Public contact	Miguel Casanovas; Medical Director, Inmunotek, S.L., 34 912908942, mcasanovas@inmunotek.com
Scientific contact	Miguel Casanovas; Medical Director, Inmunotek, S.L., 34 912908942, 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	19 December 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 December 2023
Global end of trial reached?	Yes
Global end of trial date	05 February 2024
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 allergenic extract of Juniperus oxycedrus and Cupressus arizonica that elicits a wheal of a equivalent size to that produced by a solution of histamine dihydrochlorohydrochloride at 10 mg/mL.

Protection of trial subjects:

According to GCP, written informed consent has to be obtained prior to each subject's participation in the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 December 2022
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)	29
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Positive medical history of inhalant allergy (rhinitis and/or rhinoconjunctivitis and/or asthma) to Juniperus oxycedrus and Cupressus arizonica.

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Prick test Juniperus oxycedrus

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Histamine dyhidrochloride solution
Investigational medicinal product code	
Other name	Positive control
Pharmaceutical forms	Solution for injection/skin-prick test
Routes of administration	Cutaneous use

Dosage and administration details:

10 mg/mL
One drop in duplicate on the forearm

Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	Negative control
Pharmaceutical forms	Solution for injection/skin-prick test
Routes of administration	Cutaneous use

Dosage and administration details:

One drop in duplicate on the forearm.

Investigational medicinal product name	Juniperus oxycedrus 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:

An allergen extract of Juniperus oxycedrus with a concentration of 300 µg/mL. Two dilutions of 60 and 12 µg/mL were prepared from the allergen extract. One drop in duplicate of each concentration on the forearm was tested.

Arm title	Prick test Cupressus arizonica

Arm description: -

Arm type	Experimental

Investigational medicinal product name	Histamine dyhidrochloride solution
Investigational medicinal product code	
Other name	Positive control
Pharmaceutical forms	Solution for injection/skin-prick test
Routes of administration	Cutaneous use

Dosage and administration details:

10 mg/mL. One drop in duplicate on the forearm.

Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	Negative control
Pharmaceutical forms	Solution for injection/skin-prick test
Routes of administration	Cutaneous use

Dosage and administration details:

One drop in duplicate on the forearm.

Investigational medicinal product name	Cupressus arizonica 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:

An allergen extract of Cupressus arizonica with a concentration of 100 µg/mL. Two dilutions of 20 and 4 µg/mL were prepared from the allergen extract. One drop in duplicate of each concentration on the forearm was tested.

Number of subjects in period 1	Prick test Juniperus oxycedrus	Prick test Cupressus arizonica
Started	30	30
Completed	30	30

Baseline characteristics

Reporting groups	
Reporting group title	Prick test Juniperus oxycedrus
Reporting group description: -	
Reporting group title	Prick test Cupressus arizonica
Reporting group description: -	

Reporting group values	Prick test Juniperus oxycedrus	Prick test Cupressus arizonica	Total
Number of subjects	30	30	30
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	29	29	29
From 65-84 years	1	1	1
85 years and over	0	0	0
Age continuous Units: years			
median	40	40	
standard deviation	± 11.3	± 11.3	-
Gender categorical Units: Subjects			
Female	20	20	20
Male	10	10	10

End points

End points reporting groups

Reporting group title	Prick test Juniperus oxycedrus
Reporting group description: -	
Reporting group title	Prick test Cupressus arizonica
Reporting group description: -	

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 were measured 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:

The total duration of the study for a patient was approximately 2 hours (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: Statistical results were not relevant for publish

End point values	Prick test Juniperus oxycedrus	Prick test Cupressus arizonica		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: mm2	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

The total duration of the study for a patient was approximately 2 hours.
No adverse events during the reporting period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

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 during the reporting period

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Not applicable

Notes: