



Clinical trial results:

Preventive sublingual immunotherapy for house dust mite sensitized preschool children

Summary

EudraCT number	2016-002844-18
Trial protocol	AT
Global end of trial date	16 December 2024

Results information

Result version number	v2 (current)
This version publication date	28 January 2026
First version publication date	23 October 2025
Version creation reason	• Correction of full data set Changes need to be made.

Trial information

Trial identification

Sponsor protocol code	04071962
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Zsolt Szepefalusi, PI, Dpt. of Pediatrics, Div. of Ped Pneumology, Allergy and Endocrinology, Medical University of Vienna, 0043 14040012320, zsolt.szepefalusi@meduniwien.ac.at
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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	16 December 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 December 2024
Global end of trial reached?	Yes
Global end of trial date	16 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To induce protective immunomodulation (increase of allergen-specific IgG, IgG4, TGFb, IL10) in children with IgE-sensitization to house dust mite without allergic disease manifestation at the age of 4 years

Protection of trial subjects:

children at age 4 years with house dust mite IgE-sensitization without allergic disease manifestation

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 November 2016
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	Austria: 37
Worldwide total number of subjects	37
EEA total number of subjects	37

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)	37
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Children four years of age with sensitization to house dust mite (SPT > 3mm or specific IgE > 0.35 kU/l) without clinical history of allergic symptoms are eligible for study participation: Signed informed consent, additional sensitization to max 3 other allergens, optionally atopic dermatitis with topic steroid treatment, virus preschool wheeze

Pre-assignment

Screening details:

2865 HDM-sensitized children were identified; 72 of these were at preschool age (3-5 years) and were contacted. From 39 consenting participants, 37 eligible children were included who were sensitized to HDM but had no allergy symptoms.

Period 1

Period 1 title	active phase (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	active phase

Arm description:

Using computerized 2:2 block randomization, eligible children were assigned to HDM-SLIT (Staloral®; dose: 300 index of reactivity (IR)/day) or placebo (Stallergenes-Greer, France) for 2 years (eMethod 1). Clinical assessments and blood sampling were performed at 0 month (baseline), 4-, 12-, and 24-months (end of treatment (EOT)).

Arm type	Active comparator
Investigational medicinal product name	Staloral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sublingual solution
Routes of administration	Sublingual use

Dosage and administration details:

300IR units per day over 2 years

Arm title	Placebo
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Arm description:

Using computerized 2:2 block randomization, eligible children were assigned to HDM-SLIT (Staloral®; dose: 300 index of reactivity (IR)/day) or placebo (Stallergenes-Greer, France) for 2 years (eMethod 1). Clinical assessments and blood sampling were performed at 0 month (baseline), 4-, 12-, and 24-months (end of treatment (EOT)).

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sublingual solution
Routes of administration	Sublingual use

Dosage and administration details:

300IR units per day for 2 years

Number of subjects in period 1	active phase	Placebo
Started	20	17
Completed	18	15
Not completed	2	2
Consent withdrawn by subject	2	1
left the country	-	1

Baseline characteristics

Reporting groups

Reporting group title	active phase
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Reporting group description:

Using computerized 2:2 block randomization, eligible children were assigned to HDM-SLIT (Staloral®; dose: 300 index of reactivity (IR)/day) or placebo (Stallergenes-Greer, France) for 2 years (eMethod 1). Clinical assessments and blood sampling were performed at 0 month (baseline), 4-, 12-, and 24-months (end of treatment (EOT)).

Reporting group title	Placebo
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Reporting group description:

Using computerized 2:2 block randomization, eligible children were assigned to HDM-SLIT (Staloral®; dose: 300 index of reactivity (IR)/day) or placebo (Stallergenes-Greer, France) for 2 years (eMethod 1). Clinical assessments and blood sampling were performed at 0 month (baseline), 4-, 12-, and 24-months (end of treatment (EOT)).

Reporting group values	active phase	Placebo	Total
Number of subjects	20	17	37
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)	20	17	37
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	10	10	20
Male	10	7	17

Subject analysis sets

Subject analysis set title	Induction of HDM- slgG in active treated group
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Subject analysis set type	Per protocol
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Subject analysis set description:

The primary and most secondary parameters were compared using either median or linear regression models, depending on the data skewness. Regressions models compared the time course of each value between randomized groups accounting for group, time, the interaction between time and group as fixed and subject identification number as random factor.

Reporting group values	Induction of HDM- slgG in active treated group		
Number of subjects	37		

Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	37		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Gender categorical			
Units: Subjects			
Female	20		
Male	17		

End points

End points reporting groups

Reporting group title	active phase
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Reporting group description:

Using computerized 2:2 block randomization, eligible children were assigned to HDM-SLIT (Staloral®; dose: 300 index of reactivity (IR)/day) or placebo (Stallergenes-Greer, France) for 2 years (eMethod 1). Clinical assessments and blood sampling were performed at 0 month (baseline), 4-, 12-, and 24-months (end of treatment (EOT)).

Reporting group title	Placebo
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Reporting group description:

Using computerized 2:2 block randomization, eligible children were assigned to HDM-SLIT (Staloral®; dose: 300 index of reactivity (IR)/day) or placebo (Stallergenes-Greer, France) for 2 years (eMethod 1). Clinical assessments and blood sampling were performed at 0 month (baseline), 4-, 12-, and 24-months (end of treatment (EOT)).

Subject analysis set title	Induction of HDM- sIgG in active treated group
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Subject analysis set type	Per protocol
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Subject analysis set description:

The primary and most secondary parameters were compared using either median or linear regression models, depending on the data skewness. Regressions models compared the time course of each value between randomized groups accounting for group, time, the interaction between time and group as fixed and subject identification number as random factor.

Primary: End of treatment: 2 years treatment

End point title	End of treatment: 2 years treatment
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End point description:

Primary objective of the study was to compare the change in Der p 1-sIgG from baseline to EOT by HDM-SLIT versus placebo. Secondary objectives involved assessing between- and within-group differences in the changes of i) sIgG, sIgG1, and/or sIgG4 levels for additional major HDM allergens (Der p 2 and 23), HDM-extract, and other non-treatment allergens, ii) sIgE levels for HDM-extracts and individual allergens, iii) HDM-reactivity in skin and basophils, iv) number of sensitizations to allergen-extracts (in serum and skin, combined) and individual allergens (in serum), and v) IgE-blocking functionality of children's sera.

End point type	Primary
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End point timeframe:

Primary objective of the study was to compare the change in Der p 1-sIgG from baseline to EOT by HDM-SLIT versus placebo.

End point values	active phase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	15		
Units: microgram(s)/millilitre				
median (inter-quartile range (Q1-Q3))	4.03 (2.82 to 6.66)	2.34 (0 to 2.7)		

Statistical analyses

Statistical analysis title	Baseline analysis
Comparison groups	active phase v Placebo
Number of subjects included in analysis	33
Analysis specification	Post-hoc
Analysis type	other
P-value	= 0.05
Method	Regression, Linear

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

AEs occurred in both groups but none of the participants developed a serious AE possibly-related to treatment.

Adverse event reporting additional description:

Both groups developed Serious AEs unrelated/unassignable to treatment included adenotomy, tonsillotomy, and wheezing-bronchitis episodes requiring hospitalization.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	28
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Frequency threshold for reporting non-serious adverse events: 5 %

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: AEs occurred in both groups but none of the participants developed a serious AE possibly-related to treatment.

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.

the study has interfered with the Covid19 pandemic; thus recruitment was hampered

Notes: