Clinical trial results:
A multicentre, double-blind, placebo-controlled, randomized trial to assess the efficacy and tolerability of two dosing regimens of AllerT, a combination of contiguous overlapping peptides derived from Bet v 1, in adult subjects allergic to birch pollen

Summary

EudraCT number	2011-002259-32
Trial protocol	SE LT DK LV
Global end of trial date	30 June 2013

Results information

Result version number	v1 (current)
This version publication date	01 January 2020
First version publication date	01 January 2020
Summary attachment (see zip file)	AN004T RESULTS SUMMARY (AN004T EUDRACT RESULTS.pdf)

Trial information

Trial identification

Sponsor protocol code	AN004T

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01720251
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Anergis SA
Sponsor organisation address	Route de la Corniche 4, EPALINGES, Switzerland, 1066
Public contact	Vincent Charlon, Anergis SA, +41 216519220, vincent.charlon@anergis.ch
Scientific contact	Vincent Charlon, Anergis SA, +41 216519220, vincent.charlon@anergis.ch

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 March 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 June 2013
Global end of trial reached?	Yes
Global end of trial date	30 June 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the efficacy of a two months pre-seasonal treatment with AllerT 100 µg maintenance dose in reducing symptoms of allergic rhinoconjunctivitis during the following birch pollen season

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2012
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	Poland: 86
Country: Number of subjects enrolled	Sweden: 33
Country: Number of subjects enrolled	Denmark: 46
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	Latvia: 39
Country: Number of subjects enrolled	Lithuania: 21
Country: Number of subjects enrolled	Switzerland: 2
Worldwide total number of subjects	240
EEA total number of subjects	238

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)	240
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Man or woman aged 18 to 55 years
• Presenting moderate to severe allergic rhinoconjunctivitis to birch pollen confirmed at screening by meeting all of the following criteria:
- An RSS 12 for the 2 preceding birch pollen seasons based on subject's interview by the investigator
- Previous use of anti-allergy medication during the 2 preceding b

Pre-assignment

Screening details:

Man or woman aged 18 to 55 years
• Presenting moderate to severe allergic rhinoconjunctivitis to birch pollen confirmed at screening by meeting all of the following criteria:
- An RSS 12 for the 2 preceding birch pollen seasons based on subject's interview by the investigator
- Previous use of anti-allergy medication during the 2 preceding b

Pre-assignment period milestones

Number of subjects started	240
Number of subjects completed	240

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	AllerT 100

Arm description:

AllerT 100 ug target dose

Arm type	Experimental
Investigational medicinal product name	AllerT
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

5 injections on days 1, 7, 14, 28, 56
Target doses: half dose on Day 1 and full dose on days 7, 14. 28. 56 unless adjusted due to adverse events

Arm title	AllerT 50 ug

Arm description:

AllerT target dose 50 ug

Arm type	Experimental

Investigational medicinal product name	AllerT
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

5 injections on days 1, 7, 14, 28, 56
Target doses: half dose on Day 1 and full dose on days 7, 14. 28. 56 unless adjusted due to adverse events

Arm title	placebo

Arm description:

placebo control

Arm type	Placebo
Investigational medicinal product name	placebo with alhydrogel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

placebo containing alhydrogel

Number of subjects in period 1	AllerT 100	AllerT 50 ug	placebo
Started	82	79	79
Completed	82	79	79

Baseline characteristics

Reporting groups	
Reporting group title	AllerT 100
Reporting group description:	
AllerT 100 ug target dose	
Reporting group title	AllerT 50 ug
Reporting group description:	
AllerT target dose 50 ug	
Reporting group title	placebo
Reporting group description:	
placebo control	

Reporting group values	AllerT 100	AllerT 50 ug	placebo
Number of subjects	82	79	79
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)	82	79	79
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
median	36.5	37.5	33
full range (min-max)	29 to 44	28 to 44	27 to 39
Gender categorical			
Units: Subjects			
Female	43	36	41
Male	39	43	38

Reporting group values	Total		
Number of subjects	240		
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)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	240		

From 65-84 years	0		
85 years and over	0		

Age continuous Units: years median full range (min-max)	- 		
Gender categorical Units: Subjects			
Female	120		
Male	120		

End points

End points reporting groups	
Reporting group title	AllerT 100
Reporting group description: AllerT 100 ug target dose	
Reporting group title	AllerT 50 ug
Reporting group description: AllerT target dose 50 ug	
Reporting group title	placebo
Reporting group description: placebo control	

Primary: CSMS	
End point title	CSMS
End point description:	
End point type	Primary
End point timeframe: daily combined symptom and medication score measured daily during the birch pollen season and averaged during the season defined on pollen counts in the air	

End point values	AllerT 100	AllerT 50 ug	placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	70	70	71	
Units: score				
least squares mean (standard deviation)	0.73 (± 0.583)	0.63 (± 0.512)	0.87 (± 0.616)	

Statistical analyses

Statistical analysis title	modified ITT
Comparison groups	AllerT 100 v AllerT 50 ug v placebo
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANCOVA
Parameter estimate	Mean difference (final values)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

treatment period up until 4 weeks later or till the last visit of the trial 2-4 weeks after the end of the birch pollen season

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15

Reporting groups

Reporting group title	placebo
Reporting group description: -	
Reporting group title	50 ug
Reporting group description:	
patients treated with AllerT 50 ug target dose group	
Reporting group title	100 ug
Reporting group description:	
patients treated with AllerT 100 ug target dose group	

Serious adverse events	placebo	50 ug	100 ug
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	2 / 82 (2.44%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Skull fracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity	Additional description: allergic reaction		
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	placebo	50 ug	100 ug
Total subjects affected by non-serious adverse events			
subjects affected / exposed	59 / 79 (74.68%)	70 / 78 (89.74%)	70 / 82 (85.37%)
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	53 / 79 (67.09%)	53 / 78 (67.95%)	51 / 82 (62.20%)
occurrences (all)	79	93	94
Respiratory, thoracic and mediastinal disorders			
Respiratory disorder			
subjects affected / exposed	15 / 79 (18.99%)	39 / 78 (50.00%)	47 / 82 (57.32%)
occurrences (all)	18	62	88
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	3 / 79 (3.80%)	20 / 78 (25.64%)	11 / 82 (13.41%)
occurrences (all)	3	30	19
Infections and infestations			
Rhinitis			
subjects affected / exposed	7 / 79 (8.86%)	22 / 78 (28.21%)	25 / 82 (30.49%)
occurrences (all)	8	45	54
Nasopharyngitis			
subjects affected / exposed	14 / 79 (17.72%)	13 / 78 (16.67%)	16 / 82 (19.51%)
occurrences (all)	15	16	19

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