



Clinical trial results:

A Multi-Centre, Single-Blind Study to Assess the Safety of Cat-PAD in Cat Allergic Paediatric Subjects.

Summary

EudraCT number	2014-000279-15
Trial protocol	PL
Global end of trial date	23 December 2015

Results information

Result version number	v1 (current)
This version publication date	28 February 2018
First version publication date	28 February 2018

Trial information

Trial identification

Sponsor protocol code	CP009
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01921257
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Circassia Limited
Sponsor organisation address	Robert Robinson Avenue, Oxford, United Kingdom,
Public contact	CP009-ClinicalTrialInformation-Desk, Circassia Limited, +44 1865598078, CP009ClinicalTrialInformationDesk@circassia.co.uk
Scientific contact	CP009-ClinicalTrialInformation-Desk, Circassia Limited, +44 1865598078, CP009ClinicalTrialInformationDesk@circassia.co.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001054-PIP10-03
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	12 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 December 2015
Global end of trial reached?	Yes
Global end of trial date	23 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of Cat-PAD in paediatric subjects aged 5 to <12 years.

Protection of trial subjects:

Use of MicronJet 600 TM intradermal needle

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 July 2014
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: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	16
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: -

Pre-assignment

Screening details:

Minimum of 12 and maximum of 18 to be enrolled with a history of moderate / severe allergic rhinoconjunctivitis with or without controlled asthma on exposure to cats

Period 1

Period 1 title	Placebo run-in
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Single blind ^[1]
Roles blinded	Subject, Carer

Arms

Arm title	Placebo run-in
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Cat-PAD placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Two intradermal injections of placebo (0.9% saline) given two weeks apart

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: This was a paediatric study therefore both subject and carer (parent / guardian) were blinded. All other roles were unblinded.

Number of subjects in period 1	Placebo run-in
Started	16
Completed	16

Period 2

Period 2 title	Treatment period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Single blind ^[2]
Roles blinded	Subject, Carer

Arms

Arm title	Cat-PAD
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Cat-PAD
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Eight intradermal injections of 6 nmol Cat-PAD given four weeks apart

Notes:

[2] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: This was a paediatric study therefore both subject and carer (parent / guardian) were blinded. All other roles were unblinded.

Number of subjects in period 2	Cat-PAD
Started	16
Completed	13
Not completed	3
Non specified	3

Baseline characteristics

Reporting groups

Reporting group title	Placebo run-in
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Reporting group description: -

Reporting group values	Placebo run-in	Total	
Number of subjects	16	16	
Age categorical			
Units: Subjects			
Children (2-11 years)	16	16	
Gender categorical			
Units: Subjects			
Female	6	6	
Male	10	10	

End points

End points reporting groups

Reporting group title	Placebo run-in
Reporting group description: -	
Reporting group title	Cat-PAD
Reporting group description: -	

Primary: Proportion and frequency of AEs Cat-PAD compared to placebo

End point title	Proportion and frequency of AEs Cat-PAD compared to
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End point description:

End point type	Primary
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End point timeframe:

Duration of Study

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: Descriptive statistics only

End point values	Placebo run-in	Cat-PAD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Adverse Events	5	12		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Duration of Study

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.1
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Reporting groups

Reporting group title	Placebo run-in
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Reporting group description: -

Reporting group title	Cat-PAD
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Reporting group description: -

Serious adverse events	Placebo run-in	Cat-PAD	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo run-in	Cat-PAD	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 16 (31.25%)	12 / 16 (75.00%)	
Injury, poisoning and procedural complications			

Clavicle fracture subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 1	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 7	
Immune system disorders Allergy to animal subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 2	
Gastrointestinal disorders Dyspepsia subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1 1 / 16 (6.25%) 1	1 / 16 (6.25%) 1 0 / 16 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1 0 / 16 (0.00%) 0	1 / 16 (6.25%) 1 1 / 16 (6.25%) 1	
Infections and infestations Pharyngitis subjects affected / exposed occurrences (all) Bronchitis subjects affected / exposed occurrences (all) Laryngitis subjects affected / exposed occurrences (all) Tonsillitis	1 / 16 (6.25%) 1 0 / 16 (0.00%) 0 0 / 16 (0.00%) 0	5 / 16 (31.25%) 8 2 / 16 (12.50%) 2 2 / 16 (12.50%) 2	

subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	2	
Nasopharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Otitis media			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Gastroenteritis viral			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	

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