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An early phase clinical study on the safety and potential for allergic reactions of a new vaccine to treat allergy to cats

Submission date
23/11/2022

Recruitment status
No longer recruiting

Registration date
23/06/2023

Overall study status
Completed

Last Edited
20/02/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cat allergy is a common problem, causing rhinoconjunctivitis (hayfever-like symptoms) and asthma (breathing difficulties). Allergen immunotherapy (desensitisation) for cat allergy is possible, but the process is time-consuming and carries risks of inducing an allergic reaction. This study aims to assess the safety and potential for allergic reactions (allergenicity) of a new vaccine for cat allergy in adult cat-allergic patients. The vaccine is bio-engineered to provide high-level expression of the allergenic major cat allergen but with a reduced capacity to trigger allergic reactions.

Who can participate?
Adults (male or female) aged 18-60 years with documented recent (2 years) history of cat-induced allergic rhinitis (inflammation of the nose) or rhinoconjunctivitis with or without allergic asthma

What does the study involve?
Safety will be assessed using physical exams and adverse events reporting. The allergenicity of the new investigational vaccine will be assessed by performing skin prick tests (SPTs, with the superficial puncture of the forearm skin) and intradermal injections (injection in a deeper layer of the skin) of several dilutions of a vaccine stock solution. Comparable dilutions of a commercial cat dander extract will also be administered by SPT and intradermal injections to the same subjects (but on a different forearm) for comparison purposes. Early-phase skin reactions will be measured as the size of the wheel (red, swollen mark) induced by these products 15 minutes after administration, in line with standard allergy skin testing. Because of the new vaccine technology used, it is expected that skin reactions will be less significant with the investigational product than the commercial one at comparable dilutions. This study will allow the selection of safe doses of the vaccine for future clinical studies, where proposed dosing regimens will be tested. Only one clinical site (in London, UK) will be involved in this research project. Finally, this is a short study, where only one vaccine/commercial product dilution administration session will take place, followed by a 24-hour safety assessment period.

What are the possible benefits and risks of participating?
There is no expected therapeutic benefit to the patients since this is a safety-oriented, first-in-man, single-dose study. The only true benefit is to participate in a scientific project that will contribute to the development of a new vaccine for cat allergy.
There is a risk of developing a troublesome skin wheal which can produce redness, itching, and heat on the forearm. Please note that skin wheals are expected and constitute the main secondary endpoint of this study. Wheals induced by skin prick testing are generally short-lived (less than 30 minutes) and seldom troublesome. Treatment is very seldom required in routine allergy clinical practice. If treatment is required at screening, after aeroallergen skin testing, this can be given in the form of an antihistamine cream or, if needed, an antihistamine tablet. In the case of the intervention visit, including dilutional skin prick testing and intradermal tests, the same treatment can be given at the end of the study visit. Intradermal tests may produce a longer-lasting itchy swelling of the skin, though generally this is not problematic and is expected to stop itching within 12 hours at most.
There is a potential risk of developing an anaphylactic reaction as a result of the skin testing. With SPTs, this risk is extremely low, in the region of 1 in 10,000 administrations; use of intradermal injection likely carries a higher risk than with SPT but it is nonetheless part of routine clinical allergy practice in the investigation of drug and venom allergies. Much greater dilutions of the vaccine and commercial product will be used for this route of administration than for SPTs, mitigating the risk of severe adverse reactions. Adrenaline, 0.5 mg, 1 in 1,000, is always on hand, drawn up in a syringe and ready for use during intradermal testing in the clinic at the Royal Brompton Hospital. They have ample clinical experience in identifying and treating systemic allergic reactions during drug and food challenge testing and are fully equipped to deal with the unlikely possibility of a participant developing anaphylaxis.

Where is the study run from?
Angany Innovation SAS (France)

When is the study starting and how long is it expected to run for?
November 2022 to January 2024

Who is funding the study?
Angany Innovation SAS (France)

Who is the main contact?
Dr Patrick Colin, pcolin@pcc-drugdev.com

Contact information

Type(s)
Scientific

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Integrated Research Application System (IRAS)
1006294

Central Portfolio Management System (CPMS)
53743

Protocol serial number
ANG22-01H

Study information

Scientific Title
An open label, safety and allergenicity Phase 0 study of a new hypoallergenic plant-derived cat dander vaccine in adult cat allergic subjects

Study objectives
Primary objective:
1. To test the safety of a novel vaccine for cat allergy

Secondary objectives:
1. To test the in vivo allergenicity/skin reactivity of a novel vaccine for cat allergy
2. To test the ex vivo allergenicity of a novel vaccine for cat allergy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/06/2023, Brent Research Ethics Committee (80 London Road, Skipton House, London, SE1 6LH, United Kingdom; +44 (0)20 7104 8128; brent.rec@hra.nhs.uk), ref: 22/SC/0464

Primary study design
Interventional

Study design
Non-randomized study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Allergy to cats, inducing rhino-conjunctivitis with or without asthma

Interventions
This study will compare the safety and allergenicity of two Fel d 1 allergen sources: Angany new vaccine vs the commercially available ALK Soluprick cat dander extract. All 20 study participants will receive single doses of both products in an open-label manner on their forearms using the skin prick test (SPT) as follows:

On the internal surface of one forearm: six Angany vaccine solution dilutions (from 1/180,000 to 1/1.8) as well as the undiluted solution; the vaccine diluent and a histamine solution will also be used as controls. On the internal surface of the other forearm: 5 ALK Soluprick dilutions (from 1 /100,000 to 1/10) as well as the undiluted solution; the vaccine diluent and a histamine solution will also be used as controls. Subjects will be randomized according to the dominant vs non-dominant arm receiving the vaccine using a simple randomization list. Both products will also be administered to all subjects using the intradermal route (IDT): two dilutions will be delivered, corresponding to 1/1000 and 1/100 dilutions of the previous dilutions inducing a minimum of 3 mm skin wheal size in the SPTs. All SPTs will be performed sequentially, then followed by intradermal testing (IDT); for IDTs, an adequate between-tests and between-subjects lag time will be used to assess safety. All SPTs and IDTs will be performed on the same day. Patients will be seen again 6.5 hours after the first IDT completion to re-measure the skin wheal size (late-phase reaction assessment). The first three patients enrolled will be sentinel subjects, who will be fully assessed for safety prior to further enrolment. All study subjects will be followed for a 24-hour post-discharge period for safety monitoring.

Intervention Type
Biological/Vaccine

Phase
Phase 0

Drug/device/biological/vaccine name(s)
Sterile Fel d 1 eBPs colloidal solution in 2 ml vial [Sterile Fel d 1 eBP in 2 ml vial], ALK Soluprick (cat dander) [Fel d 1 allergen]

Primary outcome(s)
Safety assessed with vital signs (blood pressure, heart rate, respiratory rate, body temperature and oxygen saturation) , physical exams, FEV-1 assessment (for sentinel subjects only) and adverse events reporting at visit day 1, pre- and post-study imp administration, and during the 24-hour post-imp administration safety follow-up period

Key secondary outcome(s)
1. Skin reactivity/allergenicity:
1.1. The early phase skin response (wheal diameter) to Fel d 1-BP in a titrated SPT and IDT compared to a commercial cat dander allergen extract, will be evaluated 15 min after vaccine IMP or commercial cat dander extract. The primary efficacy outcome will be the provocation concentration of allergen that causes a ≥5 mm skin wheal. Following SPTs and IDTs, the wheal will be outlined with a washable ink pen. the outline will then be lifted using adhesive tape applied to the skin and then transferred onto a paper recording sheet. The mean diameter of the wheal will be calculated.
1.2. The late-phase skin response following intradermal administration of Fel d 1-BP will be compared to the commercial extract at 6.5 hours after the first intradermal administration. The extent of the late-phase response will be measured using a pencil friction technique.
1.3 The provocation concentration of allergen that causes a ≥3 mm skin wheal post-SPT and post-IDT will also be determined as an additional secondary endpoint.

Completion date
12/01/2024

Eligibility

Key inclusion criteria
1. Adults (male or female) aged 18-60 years
2. Documented recent (2 years) history of cat-induced:
2.1. Moderate to severe persistent allergic rhinitis or rhinoconjunctivitis with or without:
2.2. Allergic asthma (Global Initiative for Asthma [GINA] ≤Step 3)
3. A valid positive SPT (mean wheal diameter ≥7 mm obtained after screening, duplicate cat dander extract SPT) for cat
4. Cat-specific serum immunoglobulin E (IgE) measured by ImmunoCAP (≥1 kUA/L)
5. Fel d 1 specific serum IgE measured by ImmunoCAP (≥1 kUA/L)
6. Female subjects must be:
6.1. Of non-child-bearing potential (surgically sterilized or post-menopausal [12 months with no menses without alternative medical cause]) OR
6.2. Not pregnant, non-breastfeeding or planning to become pregnant AND willing to comply with the highly effective or effective contraceptive requirements of the study from Screening to at least 28 days after the last Investigational Medicinal Product (IMP) administration. Highly effective and effective contraceptive methods include: combined hormonal contraceptives (pills, patch or vaginal ring), copper intrauterine device, tubal ligation, progestogen implant,

levonorgestrel intra-uterine releasing system and depot medroxyprogesterone acetate subcutaneous (SC) or intramuscular (IM) injections.
7. Able to speak, read and understand English sufficiently to understand the purposes and risks of the study and to provide written informed consent
8. Willing, able and available to comply with all study procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
21

Key exclusion criteria
1. History of current clinically significant gastrointestinal, hepatic, renal, cardiovascular, endocrine, oncological, immunological, neurological, ophthalmological, haematological, respiratory or psychiatric disorder or any other condition, which in the opinion of the investigator or sponsor would jeopardize the safety of the subject or the validity of the study results
2. Severe or uncontrolled asthma as assessed by the GINA Asthma symptom control questionnaire OR current treatment for asthma at GINA > Step 3 OR screening FEV1 less than 80% predicted
3. Subjects with a medical history of frequent or repeated severe or life-threatening episodes of anaphylaxis or anaphylactic shock.
4. Subjects with skin disorders that would hinder skin testing and/or its interpretation (e.g., severe generalized active atopic dermatitis)
5. Large tattoo(s) on the forearm, which could prevent the adequate assessment of wheal size, according to the investigator
6. Any medical condition in which adrenaline (epinephrine) is contraindicated

Date of first enrolment
14/09/2023

Date of final enrolment
12/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Angany Innovation SAS

Funder(s)

Funder type
Industry

Funder Name
Angany Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Raw data on primary outcomes (SPT and IDT size) will be available to coincide with data publication in a medical journal, for 1 year, shared with investigators in the field or regulatory authorities on request and with specific indications that cannot be satisfied by the published material alone. Data will be fully anonymised, and no specific additional consent was requested from participants beyond fully anonymised data being published in a scientific journal (s). The data would be available from the sponsor, Angany Inc., more specifically from Patrick Colin (pcolin@pcc-drugdev.com) as a Sponsor Representative.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results		28/04/2024	20/02/2025	No	No
Protocol file	version 4.0	15/01/2023	29/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes