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A Nasal Allergen Challenge (NAC) study to evaluate the effects of SMP-028 on the release of inflammatory mediators in subjects with allergic rhinitis out of season

Submission date
21/09/2009

Registration date
11/11/2009

Last Edited
21/07/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
D4050092

Study information

Scientific Title
An exploratory, randomised, double-blind, placebo-controlled, 14-day, three-way crossover study, followed by an open label 1 day period when subjects will be dosed with intranasal fluticasone, nasal allergen challenge (NAC) study to evaluate the effects of SMP-028 on the release of inflammatory mediators after NAC with timothy grass pollen in subjects with allergic rhinitis out of season

Acronym
NAC SMP-028

Study objectives
Primary:
To assess the pharmacodynamic (PD) response to a standardised nasal allergen challenge (NAC) with timothy grass pollen following multiple doses of SMP-028 in subjects with allergic rhinitis out of season.

Secondary:
1. To evaluate the effects of multiple doses of SMP-028 on allergic rhinitis symptoms after NAC
2. To evaluate the safety and tolerability of 14 days of dosing of SMP-028
3. To evaluate the multiple dose pharmacokinetics (PK) of SMP-028

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 21/05/10:
The Royal Free Hospital & Medical School Research Ethics Committee approved on the 17th of December 2009 (ref: D4050092 [NAC])

Study design
Exploratory randomised double-blind placebo-controlled crossover study, followed by an open label 1 day period

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Allergic rhinitis

Interventions
Subjects will be randomly assigned to one of two treatment groups. Within each group the subjects will receive two oral dosing regimens of SMP-028 and placebo.

Group A: SMP-028 40 mg once daily, SMP-028 160 mg once daily and placebo once daily
Group B: SMP-028 10 mg twice daily, SMP-028 80 mg twice daily and placebo twice daily
On Day 14: Only a single dose will be administered in the morning. Any remaining dose for that day will not be taken by the subject (e.g. Group B subjects).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
SMP-028

Primary outcome measure
Pharmacodynamic endpoints:
1. Post-NAC nasal filter paper levels of chemical mediators and cytokines
2. Nasal lavage fluid eosinophil, neutrophil and monocyte counts (number/mm^3)

Clinical and PK endpoints:
3. Total nasal symptom score after NAC
4. Multiple dose PK of SMP-028

Safety endpoints:
5. Adverse events
6. Standard laboratory safety tests
7. Vital signs
8. Physical examinations
9. 12-lead electrocardiogram (ECG)
10. Hormone laboratory tests

All endpoints are followed up to day 14 apart from safety which will be followed up until 10 days +/- 3 days after the last treatment period.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2009

Completion date
01/04/2010

Eligibility

Key inclusion criteria
1. Male or female (non-child bearing potential) subjects aged 18 to 55 years old with atopy to timothy grass pollen
2. Asymptomatic as characterised by a normal appearing nasal mucosa with no active allergic rhinitis at screening and on day 1 of each treatment period
3. An eosinophilic nasal response after NAC with timothy grass pollen at the screening visit
4. Body mass index (BMI) within the range 19.0 - 32.0 kg/m^2 (inclusive)
5. Pre-bronchodilator forced expiratory volume in 1 second (FEV1) greater than 90% of predicted at screening

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
Approximately 40 completed subjects (two groups of 20 subjects)

Key exclusion criteria
1. Past or present disease which, as judged by the Investigator, may affect the outcome of this study
2. Past or present nasal condition which may affect the outcome of the study
3. Bacterial or viral infection of the upper/lower airways, sinus, or ear
4. History of being unable to tolerate or complete NAC tests
5. Subject is undergoing or has undergone desensitisation therapy

Date of first enrolment
01/11/2009

Date of final enrolment
01/04/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Respiratory Clinical Trials Ltd (TCT)
London
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W1G 8HU

Sponsor information

Organisation
Dainippon Sumitomo Pharma Europe Ltd (UK)

Sponsor details
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Sponsor type
Industry

Website
http://www.ds-pharma.co.jp/english

ROR
https://ror.org/03sh4z743

Funder(s)

Funder type
Industry

Funder Name
Dainippon Sumitomo Pharma Co. Ltd (Japan)

Alternative Name(s)
Dainippon Sumitomo Pharma Co., Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Japan

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration