

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	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 11/11/2009	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 21/07/2016	Condition category Respiratory	☐ 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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Contact details

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Additional identifiers

Protocol serial number

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])

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

Pharmacodynamic endpoints:

1. Post-NAC nasal filter paper levels of chemical mediators and cytokines
2. Nasal lavage fluid eosinophil, neutrophil and monocyte counts (number/mm³)

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.

Key secondary outcome(s)

No secondary outcome measures

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/m² (inclusive)
5. Pre-bronchodilator forced expiratory volume in 1 second (FEV1) greater than 90% of predicted at screening

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Respiratory Clinical Trials Ltd (TCT)

London

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Sponsor information**Organisation**

Dainippon Sumitomo Pharma Europe Ltd (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration