

# 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

<b>Submission date</b> 21/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/07/2016	<b>Condition category</b> Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Brian Leaker

**Contact details**  
Respiratory Clinical Trials Ltd (TCT)  
Heart Lung Centre  
Queen Anne Street Medical Centre  
18-20 Queen Anne Street  
London  
United Kingdom  
W1G 8HU

## 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])

## Study design

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

## Primary study design

Interventional

## 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/mm<sup>3</sup>)

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/m<sup>2</sup> (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

United Kingdom

W1G 8HU

## **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