

# An Inhaled Allergen Challenge (IAC) study to evaluate the effects of SMP-028 in subjects with mild to moderate asthma

<b>Submission date</b> 21/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/07/2016	<b>Condition category</b> Respiratory	<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 (RCT)  
Heart Lung Centre  
Queen Anne Street Medical Centre  
18-20 Queen Anne Street  
London  
United Kingdom  
W1G 8HU

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
D4050169

# Study information

## Scientific Title

An exploratory, randomised, double-blind, placebo controlled, 14 day, two-way crossover, Inhaled Allergen Challenge (IAC) study to evaluate the effects of SMP-028 in subjects with mild to moderate asthma

## Acronym

IAC SMP-028

## Study objectives

Primary:

To evaluate the effect on the late asthmatic response (LAR) to Inhaled Allergen Challenge in mild to moderate asthmatic subjects.

Secondary:

1. To evaluate the effect on the early asthmatic response (EAR), pharmacodynamics and lung function to Inhaled Allergen Challenge in mild to moderate asthmatic subjects
2. To evaluate the effect on bronchial hyper-reactivity as measured by adenosine monophosphate (AMP) challenge
3. To assess the safety and tolerability of treatment with repeat doses of SMP-028 in mild to moderate asthmatic subjects
4. To evaluate the multiple dose pharmacokinetics of SMP-028 and metabolites in subjects with mild to moderate asthma

## 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 1st of October 2009 (ref: D4050169 [IAC])

## Study design

Exploratory randomised double-blind placebo-controlled two-way crossover trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## 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**

Asthma

### **Interventions**

On Days 1 - 13, the dose of SMP-028 will be 80 mg twice a day or placebo. A single morning dose of 80 mg SMP-028 or placebo will be taken on Day 14.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

SMP-028

### **Primary outcome measure**

Mean baseline-corrected area under the forced expiratory volume in 1 second (FEV1) reduction curve from 4 to 10 hours after allergen challenge.

### **Secondary outcome measures**

1. Early Asthmatic Response: FEV1
2. Exhaled NO
3. AMP PC20
4. Induced sputum cell counts
5. induced sputum inflammatory mediators
6. Adverse events
7. Laboratory safety tests
8. Vital signs
9. Physical examinations
10. 12-lead ECGs (electrocardiograms)
11. Pharmacokinetics of SMP-028 and its metabolites

Measured on Day 13/14 as appropriate. In addition, safety is followed up until 10 days +/- 3 days after the last dose on Day 14 of Period 2.

### **Overall study start date**

01/11/2009

### **Completion date**

01/04/2010

## **Eligibility**

### **Key inclusion criteria**

1. Male or female (of non childbearing potential) subjects aged between 18 and 65 years who have documented history of bronchial asthma

2. Demonstration of a positive wheal reaction to at least 1 of 3 allergens (house dust mite, grass pollen, cat hair and dander) on skin prick testing
3. Screening allergen challenge demonstrating that the subject experiences both an early and late asthmatic response.
4. Body mass index (BMI) within the range 19.0 - 32.0 kg/m<sup>2</sup> (inclusive)
5. Sensitivity to AMP with a provocative concentration of AMP

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

Approximately 24 subjects in order to ensure 20 completed subjects

**Key exclusion criteria**

1. Past or present disease which, as judged by the Investigator, may affect the outcome of this study
2. Subject has known history of uncontrolled hypertension or is hypertensive at the Screening visit
3. Respiratory tract infection and/or exacerbation of asthma within 4 weeks prior to the first dose of study drug
4. Symptomatic allergic rhinitis
5. History of life-threatening asthma

**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 (RCT)**

London

United Kingdom

W1G 8HU

## Sponsor information

**Organisation**

Dainippon Sumitomo Pharma Europe Ltd (UK)

**Sponsor details**

1st Floor, Southside

97-105 Victoria Street

London

United Kingdom

SW1E 6QT

**Sponsor type**

Industry

**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