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

Submission date 21/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/11/2009	**Overall study status** Completed	
Last Edited 21/07/2016	**Condition category** Respiratory	

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
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^2 (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
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United Kingdom
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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