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SMP-028/ketoconazole drug: drug interaction study

Submission date	Recruitment status	[ ] Prospectively registered
19/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/07/2016	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ds-pharma.co.jp/english

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
D4050156

Study information

Scientific Title
An exploratory, randomised, open-label, two-period, crossover study in healthy subjects to evaluate the effect of ketoconazole on the pharmacokinetics of SMP-028

Study objectives
Primary aim:
To assess the effects of administration of the CYP3A4 inhibitor, ketoconazole, on the single dose pharmacokinetic (PK) profile of SMP-028 in healthy subjects.

Secondary aim:
To assess the safety and tolerability of SMP-028 when co-administered with the CYP3A4 inhibitor, ketoconazole.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Capenhurst Independent Research Ethics Committee, 16/03/2010

Study design
Randomised open-label two-period crossover study in healthy subjects

Primary study design
Interventional

Secondary study design
Randomised cross over 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 subject information sheet

Health condition(s) or problem(s) studied
Asthma

Interventions
Subjects will be randomised (in a 1:1 ratio) into one of two treatment sequences (Treatment A followed by Treatment B or Treatment B followed by Treatment A):
Treatment A consists of Ketoconazole 400 mg daily, administered orally twice a day on Days 1 to 7 followed by a single oral dose of SMP-028 20 mg on the morning of Day 5.
Treatment B consists of a single dose of SMP-028 20 mg on Day 1.
Subjects will be followed up for 8 days after dosing in Treatment A and 4 days in Treatment B.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Pharmacokinetics:
1. Primary endpoints:
Comparative SMP-028 exposure between treatment periods (AUC[0-∞] and C[max]) over 72 hours
2. Secondary endpoints:
Comparative SMP-028 exposure between treatment periods (other pharmacokinetic parameters), and exposure levels of the metabolites of SMP-028 over 72 hours

Secondary outcome measures
Safety endpoints:
1. The proportion of subjects with adverse events (AEs)
2. Changes in standard laboratory safety tests
2.1. haematology
2.2. clinical chemistry
2.3. urinalysis
3. Concomitant medication review
4. Vital signs
5. Complete physical examinations
6. 12-lead ECG

Overall study start date
18/03/2010

Completion date
30/06/2010

Eligibility

Key inclusion criteria
Healthy subjects aged 18 to 55 years who are in good health as determined by past medical history, physical examination, electrocardiogram, clinical safety laboratory tests and urinalysis

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
32 healthy subjects (16 in each group). In order to obtain 32 completers, it is estimated that 34 subjects will be enrolled.

Key exclusion criteria
Standard exclusion criteria for a healthy volunteer study

Date of first enrolment
18/03/2010

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dainippon Sumitomo Pharma Europe Ltd
London
United Kingdom
SW1E 6QT

Sponsor information

Organisation
Dainippon Sumitomo Pharma Europe Ltd (UK)

Sponsor details
c/o Noreen O'Connor, PhD
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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