

SMP-028/ketoconazole drug: drug interaction study

Submission date 19/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/07/2016	Condition category 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 Noreen O'Connor

Contact details
Dainippon Sumitomo Pharma Europe Ltd
1st Floor, Southside
97-105 Victoria Street
London
United Kingdom
SW1E 6QT

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes