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SMP-028/midazolam drug: drug interaction study

Submission date 19/03/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/04/2010	**Overall study status** Completed	
Last Edited 02/08/2016	**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

Protocol serial number
D4050157

Study information

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

Study objectives

1. Primary:
To assess the effect of repeat dose administration of SMP-028 on the single-dose pharmacokinetic (PK) profile of the CYP3A4 substrate, midazolam, in healthy subjects
2. Secondary:
2.1. To assess the safety and tolerability of SMP-028
2.2. To assess the safety and tolerability of the co-administration of SMP-028 and the CYP3A4 substrate midazolam

Ethics approval required
Old ethics approval format

Ethics approval(s)
Capenhurst Independent Research Ethics Committee, 16/03/2010, ref: 10/IEC01/4 [D4050157]

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 oral SMP-028 200 mg once daily in the morning on Days 1 to 5. Single dose of midazolam 7.5 mg orally on the morning of Day 5.
Treatment B consists of a single dose of midazolam 7.5 mg orally on Day 1.
Subjects will be followed up for 7 days in Treatment A and 3 days in Treatment B.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Pharmacokinetics:
1. Primary endpoints:
Comparative midazolam exposure between treatment periods (AUC[0-∞] and C[max]) over 24 hours
2. Secondary endpoints:
Comparative midazolam exposure between treatment periods (other pharmacokinetic parameters), and exposure levels of the active metabolite α-hydroxymidazolam over 24 hours.

Key secondary outcome(s))
2. Safety:
2.1. The proportion of subjects with adverse events (AEs)
2.2. Changes in standard laboratory safety tests:
2.2.1. Haematology
2.2.2. Clinical chemistry
2.2.3. Urinalysis
2.3. Concomitant medication review
2.4. Vital signs
2.5. Complete physical examinations
2.6. 12-lead ECG

Completion date
31/07/2010

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
20/05/2010

Date of final enrolment
31/07/2010

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?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes