

# SMP-028/midazolam drug: drug interaction study

<b>Submission date</b> 19/03/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 15/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 02/08/2016	<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 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**  
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<sub>[0-∞]</sub> and C<sub>[max]</sub>) 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes