

# SMP-028/Oral Contraceptive Drug: Drug Interaction study

<b>Submission date</b> 04/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/05/2010	<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

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## Additional identifiers

**Protocol serial number**  
D4050158

## Study information

**Scientific Title**  
A randomised, double-blind, placebo-controlled, two-sequence, two-period, crossover study to evaluate the effect of SMP-028 on oral contraceptive pharmacokinetics in healthy female subjects

## Acronym

OC-DDI

## Study objectives

Primary:

To evaluate the effect of co-administration of SMP-028 on the pharmacokinetic (PK) profile of Microgynon 30®.

Secondary:

1. To evaluate the PK profile of SMP-028 in healthy female subjects taking Microgynon 30®
2. To evaluate the effect of co-administration of SMP-028 on the pharmacodynamic (PD) response to Microgynon 30®
3. To assess the safety and tolerability of co-administration of SMP-028 and Microgynon 30® in healthy female subjects

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Added 21/05/10:

The Independent Ethics Committee of the Foundation Evaluation of Ethics in Biomedical Research Assen approved on the 11th of January 2010 (ref: D4050158 [OC-DDI])

## Study design

Randomised double-blind placebo-controlled two-sequence two-period crossover study

## Primary study design

Interventional

## Study type(s)

Treatment

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

Asthma

## Interventions

Subjects will receive Microgynon 30® (or another brand of the OC pill containing equivalent components) during a 2 cycle synchronisation period. Subjects will continue to receive Microgynon 30® on days 1 to 21 of both treatment periods. Subjects will also receive either SMP-028 (160 mg) once daily or matching placebo on Days 1 to 21 of each treatment period. Each subject will receive SMP-028 for one treatment period, placebo for the other treatment period.

## Intervention Type

Drug

## Phase

Phase I

## Drug/device/biological/vaccine name(s)

SMP-028, Microgynon 30®

**Primary outcome(s)**

1. Pharmacokinetics: Drug exposure of the components of Microgynon 30® (ethinylestradiol [EE] and levonorgestrel [LNG]) as measured by serum AUC<sub>0-tlast</sub> and C<sub>max</sub> of EE and LNG on day 21
2. Pharmacodynamics:
  - 2.1. Clotting times (e.g. prothrombin and activated partial thromboplastin times) measured at day 21
  - 2.2. Maximum follicular diameter at day 21
  - 2.3. Serum oestradiol, FSH, LH and progesterone levels taken at day 14 and 21
  - 2.4. Sex hormone binding globulin (SHBG) at day 21

**Key secondary outcome(s)**

1. Pharmacokinetics:
  - 1.1. Drug exposure of SMP-028 as measured by serum AUC<sub>0-tlast</sub>, and C<sub>max</sub> on day 21
  - 1.2. Other PK parameters including T<sub>max</sub>, AUC<sub>0-8</sub>, λ<sub>Z</sub>, t<sub>1/2</sub>, MRT, CL/F and V<sub>z</sub>/F for SMP-028, EE and LNG on day 21
2. Safety endpoints:
  - 2.1. Incidence and severity of adverse events (AEs)
  - 2.2. Discontinuations due to AEs
  - 2.3. Actual values and changes in values from baseline in standard laboratory safety tests, vital signs, physical examinations and 12-lead ECGs (electrocardiograms)

Subjects will be provided with subject diary to record timing of OC intake and details of vaginal bleeding.

**Completion date**

30/06/2010

**Eligibility****Key inclusion criteria**

1. Healthy female subjects aged 18 to 45 years
2. In good health as determined by:
  - 2.1. Past medical history
  - 2.2. Physical examination
  - 2.3. Electrocardiogram
  - 2.4. Clinical safety laboratory tests
  - 2.5. Urinalysis

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Key exclusion criteria**

1. Contraindications to the administration of a combined oral contraceptive (OC) pill
2. Other standard exclusion criteria

**Date of first enrolment**

14/01/2010

**Date of final enrolment**

30/06/2010

**Locations****Countries of recruitment**

United Kingdom

England

Netherlands

**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="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes