

SMP-028/Oral Contraceptive Drug: Drug Interaction study

Submission date 04/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/01/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/05/2010	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
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_{0-tlast} and C_{max} 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_{0-tlast}, and C_{max} on day 21
 - 1.2. Other PK parameters including T_{max}, AUC₀₋₈, λ_Z, t_{1/2}, MRT, CL/F and V_Z/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