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SMP-028/Oral Contraceptive Drug: Drug Interaction study

Submission date	Recruitment status	[ ] Prospectively registered
04/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/01/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/05/2010	Respiratory	[ ] 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])

Primary study design
Interventional

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

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 AUC0-tlast and Cmax of EE and LNG on day 21
2. Pharmcodynamics:
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 AUC0-tlast, and Cmax on day 21
1.2. Other PK parameters including Tmax, AUC0-8, λZ, t1/2, MRT, CL/F and Vz/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