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DSP-2230 Capsaicin and UVB Challenge Study

Submission date 28/11/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 17/12/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/06/2017	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
DSP-2230 is a new drug that has shown promising results in reducing the feeling of pain. The main aim of the study is to investigate the response of the skin on experiencing pain and to assess the painkilling properties of DSP-2230 which, it is hoped, will be helpful in treating a condition called peripheral neuropathic pain.

Who can participate?
Healthy men aged 18 to 55 years.

What does the study involve?
The study is undertaken in two parts, but you will only participate in one part of the study. If you are in Part 1 you will receive an injection of capsaicin to produce a redness of the skin accompanied by pain and increased sensitivity. You will attend two screening visits before the main study starts to assess your response to two capsaicin injections 4 hours apart. The main part of the study will involve four main study periods. You will stay overnight for two nights in the Clinical Unit on each of the four study periods, followed by a morning visit on Days 3 and 4. During this time you will be randomly allocated to receive a dose of the study drug or a placebo (dummy drug) as a suspension in water or a dose of pregablin or placebo as capsules. You will also give blood and urine samples, have your vital signs measured, receive a capsaicin injection and undergo pain assessments.
In Part 2 we will use ultraviolet radiation to produce an area of redness similar to sunburn and increased sensitivity to pain. You will attend two screening visits before the main study starts to undergo ultraviolet irradiation heat pain tests, carried out using a thermode (heated metal plate) and performed on your left thigh. The main part of the study will involve four main study periods. You will stay overnight for two nights in the Clinical Unit on each of the four study periods, followed by a morning visit on Days 3 and 4. During this time you will receive a dose of the study drug or placebo as a suspension or a dose of ibuprofen lysine or placebo as capsules. You will also give blood and urine samples, have your vital signs measured and undergo the heat pain test. There will be a follow-up visit for all subjects 8-11 days after receiving the last dose of the study drug.

What are the possible benefits and risks of participating?
You will not receive any direct medical benefit from participating in this study, but a potential benefit could be the detection of an unsuspected medical condition from the tests performed.

You may feel discomfort during some of the tests or experience some inconvenience. Drawing blood from your arm may cause pain, bruising, light headedness and (rarely) infection. Since DSP-2230 is an investigational drug, there may be some unexpected side effects

Where is the study run from?
This research is being run by ICON Development Solutions (UK).

When is the study starting and how long is it expected to run for?
From January to April 2013.

Who is funding the study?
The study is funded by Dainippon Sumitomo Pharma Europe Ltd.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
D8450055

Study information

Scientific Title
A randomised, double-blind, placebo-controlled, four-way crossover, two-part study investigating the pharmacodynamic effect of DSP-2230 using the ID Capsaicin and UVB models in healthy male subjects, using pregabalin and ibuprofen lysine as positive controls.

Study objectives
1. To determine the PD effects of DSP 2230 using the intradermal (ID) capsaicin model in healthy subjects
2. To determine the PD effects of DSP 2230 using the Ultraviolet B (UVB) model in healthy subjects
3. To assess the safety and tolerability of single doses of DSP 2230 in healthy subjects
4. To assess the single dose pharmacokinetics (PK) of DSP 2230 in healthy subjects
5. To assess the single dose PK/PD relationship of DSP 2230, if possible

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee

Study design
Randomised double-blind double dummy placebo-controlled single dose four-way crossover design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Peripheral Neuropathic Pain

Interventions
Part 1 - ID capsaicin model:
ID capsaicin 100mg administered ID in 100ml of solution.
Pregabalin 300 mg orally administered.
Pregabalin placebo orally administered.
The DSP-2230 placebo oral suspension.

Part 2 - UVB model:
An 800 mg dose ibuprofen (as ibuprofen lysine 342 mg, orally delivering a 200 mg dose of ibuprofen per tablet). Ibuprofen placebo orally administered.
The DSP-2230 placebo oral suspension.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pregabalin, ibuprofen

Primary outcome measure
Safety:
Parts 1 and 2: Adverse events (AEs), serious AEs (SAEs), vital signs, electrocardiogram (ECG) and ECG time intervals, clinical chemistry, haematology and urinalysis including biomarkers of renal function.
Pharmacodynamic:
Part 1 - ID capsaicin model: Subjective rating of pain using a visual analogue scale (VAS), area of punctate hyperalgesia, area of brush-evoked allodynia, area of vascular flare using laser Doppler flowmetry, intensity and area of cutaneous blood flow using laser Doppler flowmetry.

Part 2 - UVB model: Heat pain detection threshold (HPDT), heat pain tolerance threshold (HPTT), area of vascular flare using laser Doppler flowmetry, intensity and area of cutaneous blood flow using laser Doppler flowmetry.
Pharmacokinetic:
Parts 1 and 2: Plasma single dose PK of DSP-2230 and its metabolite

Secondary outcome measures
No secondary outcome measures

Overall study start date
07/01/2013

Completion date
30/04/2013

Eligibility

Key inclusion criteria
All subjects (males) will be in good health aged 18 - 55 years with no evidence of systemic disease and be able to comply with all aspects of the protocol and able to give written informed consent to participate in the study.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
A total of 56 subjects will be randomised into the study, 28 in Part 1 and 28 in Part 2, to ensure that 24 subjects complete each part.

Key exclusion criteria
All subjects will not have, or have had a history of, clinically significant neurological, gastrointestinal, renal, hepatic, cardiovascular, psychological, pulmonary, metabolic, endocrine, haematological or other major disorders. They will not have, or have had a history of, drug or alcohol abuse and will not have participated in a clinical study with an investigational medicinal product (IMP) within 3 months of randomisation into the current study and will not have donated or lost > 500 mL of blood or blood products in the 3 months preceding the start of dosing.

Date of first enrolment
07/01/2013

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
ICON Development Solutions
Manchester
United Kingdom
M15 6SH

Sponsor information

Organisation
Sunovion Pharmaceuticals Europe Ltd

Sponsor details
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United Kingdom
SW1E 6QT

Sponsor type
Industry

Website
http://www.sunovion.eu/

ROR
https://ror.org/03sh4z743

Funder(s)

Funder type
Industry

Funder Name
Sunovion Pharmaceuticals Europe Ltd

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration