

DSP-2230 Capsaicin and UVB Challenge Study

Submission date 28/11/2012	Recruitment status No longer recruiting	☒ 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?

Dr Peter Dewland

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Contact information

Type(s)

Scientific

Contact name

Dr Peter Dewland

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

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

United Kingdom

England

Study participating centre

ICON Development Solutions

Manchester

United Kingdom

M15 6SH

Sponsor information

Organisation

Sunovion Pharmaceuticals Europe Ltd

ROR

<https://ror.org/03sh4z743>

Funder(s)

Funder type

Industry

Funder Name

Sunovion Pharmaceuticals Europe Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration