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Study to assess the safety, tolerability and pharmacokinetics of DSP-2230 in humans

Submission date
18/04/2012

Recruitment status
No longer recruiting

Registration date
23/05/2012

Overall study status
Completed

Last Edited
27/06/2016

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 in animal models. The main aim of the study is to assess the safety of the drug in humans and how well the drug is tolerated when given as single increasing doses to healthy male and female volunteers. In addition, the drug levels in the body and how fast the drug and its breakdown products get into and out of the blood system will also be investigated.

Who can participate?
Healthy men and women aged 18 to 55 years

What does the study involve?
The study involves 3 parts but volunteers only choose to participate in one part. Volunteers will attend a screening visit which will take place up to 21 days before the main study starts. They will have a full medical examination. They will have blood and urine tests which involve taking blood samples. If volunteers decide to take part in the main part of the trial, they will attend the Unit on several occasions as follows:
Part 1: 4 times, one of which will involve staying in the centre for 4 continuous nights.
Part 2: 3 times, one of which will involve staying in the centre for 4 continuous nights.
Part 3: 4 times, one of which will involve staying in the centre for 17 continuous nights.
During this time you will receive study drug or placebo and have blood and urine samples taken. You will also have your vital signs measured and be asked to perform a set of cognitive function tests.

What are the possible benefits and risks of participating?
Volunteers 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 tests performed. Volunteers may feel discomfort during some of the tests or experience some inconveniences. 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?
ICON Development Solutions, Manchester, United Kingdom

When is study starting and how long is it expected to run for?
May 2012 to December 2012

Who is funding the study?
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
ICON Development Solutions
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
D8450052

Study information

Scientific Title
A phase I, three part study, in healthy subjects to assess the safety, tolerability and pharmacokinetics of single and multiple doses of DSP-2230, and the effect of the administration in the fed and fasted states on the pharmacokinetics of DSP-2230.

Study objectives
Three stages:
1. To assess the safety, tolerability and PK of single ascending doses of DSP-2230

2. To assess the effect of the administration of DSP-2230 in the fed and fasted states on the PK of DSP-2230
3. To assess the safety, tolerability and PK of multiple ascending doses of DSP-2230 after 14 days of dosing

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Parts 1 & 3 = randomised double-blind placebo-controlled escalating dose sequential trial
Part 2 = randomised open-label 2-way crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use the contact details below to request a subject information sheet

Health condition(s) or problem(s) studied
Peripheral neuropathic pain

Interventions
Part 1: A single dose of DSP-2230 or placebo will be orally administered in the fasted state. Dose for the first cohort of Part 1 will not exceed 3mg
Part 2: DSP-2230 will be orally administered.
Part 3: DSP-2230 or placebo will be orally administered in the fed state for up to 14 days.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
DSP-2230

Primary outcome measure

1. Safety - Adverse Events (AEs)
2. Serious Adverse Events (SAEs)
3. Vital signs
4. Electrocardiogram (ECG)
5. ECT time intervals
6. Clinical chemistry, haematology and urinalysis
7. Pharmacokinetic - Plasma and urinary PK parameters of DSP-2230 and its metabolite
8. Pharmacodynamic - Pharmacodynamic parameters of the cognitive test battery

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/05/2012

Completion date
15/01/2013

Eligibility

Key inclusion criteria
1. Males and females of non-childbearing potential [Parts 1 and 2]
2. Females of childbearing potential [Part 3]
3. In good health
4. Aged 18 to 55 years
5. No evidence of systemic disease
6. Able to comply with all aspects of the protocol
7. Able to give written informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Part 1: 72 subjects; Part 2: 12 subjects; Part 3: 72 subjects - Total 156 subjects.

Key exclusion criteria
1. All subjects will not have, or have had a history of, clinically significant neurological, gastrointestinal, renal, hepatic, caridovascular, psychological, metabolic, endocrine, haematological or other major disorders
2. They will not have, or have had a history of, drug or alcohol abuse
3. They will not have participated in a clinical study with an investigational medicinal product

(IMP) within 3 months of randomisation into the current study
4. They will not have donated or lost >500mL of blood or blood products in the 3 months preceding the start of dosing

Date of first enrolment
15/05/2012

Date of final enrolment
15/01/2013

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
c/o Dr Noreen OConnor
Southside
97-105 Victoria Street
London
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