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A study on the safety and effectiveness of the new investigational drug ODM-111 when given to healthy volunteers, and how ODM-111 is absorbed and processed by the human body.

Submission date
20/10/2022

Recruitment status
No longer recruiting

Registration date
25/10/2022

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
ODM-111 is a new drug that could potentially be used in the treatment of acute and long-term pain. ODM-111 blocks sodium (ion) channels in the nerves that transmit pain signals to the brain. This should help patients with pain.
The purpose of the this study is to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ODM-111to determine whether further clinical studies in patients with pain is warranted.

Who can participate?
Healthy males and females between 18 and 55 years

What does the study involve?
Assessments of safety, tolerability and efficacy on pain thresholds for ODM-111 in healthy volunteers.

What are the possible benefits and risks of participating?
Subjects might experience AEs related to the study drug or procedural complications e.g., blood draws, slight skin irritation from the adhesive on the ECG electrodes, short lasting pain from experimental pain testing. This phase 1 study is the initial study in humans to test the tolerability and safety of this potential pain therapeutic and requires healthy volunteers willing to participate in this research. As subjects participating in this clinical study are healthy, they will not benefit from administration of ODM-111.

Where is the study run from?
Centre for Human Drug Research (Netherlands)

When is the study starting and how long is it expected to run for?
January 2022 to December 2023

Who is funding the study?
Orion Corporation (Finland)

Who is the main contact?
I. Koopmans, Project leader (ikoopmans@chdr.nl)

Contact information

Type(s)
Public

Contact name
Miss Ingrid Koopmans

ORCID ID
https://orcid.org/0000-0003-4199-9781

Contact details
Zernikedreef 8
Leiden
Netherlands
2333 CL
+31 71 5246 400
clintrials@chdr.nl

Additional identifiers

Clinical Trials Information System (CTIS)
2022-002251-19

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CHDR2228 / 3133001

Study information

Scientific Title
Safety, tolerability, pharmacokinetic and pharmacodynamic effects of single and multiple escalating doses ofODM-111 and effect of food on the pharmacokinetics of ODM-111.

Acronym
FIMCARE

Study objectives
The purpose of the proposed study is to investigate safety, tolerability, pharmacokinetics and pharmacodynamics of ODM-111 to determine whether further clinical studies in patients with pain is warranted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/08/2022, Stichting BEBO (Doctor Nassaulaan 10, 9401 HK Assen, The Netherlands; +31 592-405871; info@stbebo.nl), ref: NL81806.056.22

Study design
Phase 1 randomized double-blind placebo-controlled single centre first-in-man study in healthy subjects with open-label food effect cohort and a single-dose crossover part.

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Novel treatment against chronic-/neuropathic pain.

Interventions
Test product: ODM-111 50 mg and 200 mg tablets.
Part I: 7 escalating single dose levels of ODM-111are planned to be administered. The planned dose levels may be modified by the DEC based on emerging data. Dose level to be administered for the food-effect cohort will be decided based on the prior fasted data following establishment of safety and tolerability at a dose ≥ 2-fold above the planned food-effect dose.
Part II: 3 escalating dose levels of ODM-111are planned to be administered. The doses, frequency of dosing and dosing under fasted or fed state will be decided by the DEC based on the review of Part I data and the data for the previous dose level in the Part II.
Part III: Single dose of ODM-111 and placebo will be administered in a randomised order. The dose and dosing under fasted or fed state will be decided by the DEC based on the review of Part I data.
Reference product: Placebo ODM-111tablets

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
ODM-111

Primary outcome(s)
The concentration of ODM-111 is measured throughout the 24 hours after dosing.

Key secondary outcome(s))
Pain is measured using a VAS at several timepoints after dosing.

Completion date

06/12/2023

Eligibility

Key inclusion criteria
1. Written informed consent (IC) obtained
2. Good general health ascertained by detailed medical history and laboratory and physical examinations.
3. Males and females between 18 and 55 years (inclusive).
4. Body mass index (BMI) between 18-32 kg/m² (inclusive).
5. Weight 50-120 kg (inclusive).
6. Female participants with fertile male partner, and male participants with female partners of child-bearing potential, must adhere to a highly effective form of contraception (e.g. combined or progestogen only hormonal contraceptives associated with inhibition of ovulation, intrauterine devices or intrauterine hormone-releasing system), if sexually active and not permanently sterilised, for females from 4 weeks before the first study treatment administration, and for males from admission to study centre until 3 months after the end-of-study visit. Additionally, women who are postmenopausal (1 year since last menstrual cycle) are considered not to be reproductive and can be included. For male subjects, sperm donation is not allowed until 3 months after the end-of-study visit.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Key exclusion criteria
1. A predictable poor compliance or inability to understand and comply with protocol requirements, instructions and protocol-stated restrictions or communicate well with the investigator
2. Veins unsuitable for repeated venipuncture or for cannulation.
3. Evidence of clinically significant cardiovascular, renal, hepatic, haematological, gastro-intestinal, pulmonary, immunologic, dermatologic, metabolic-endocrine, neurological, urogenital, psychiatric and/or other major disease as judged by the investigator. Any surgical or medical condition (including cholecystectomy) which might significantly alter the absorption, distribution, metabolism or excretion of any drug.
4. Part I and Part III: Any current, clinically significant, known medical condition that would affect

sensitivity to cold(such as atherosclerosis, Raynaud's disease, urticaria, hypothyroidism) or pain
5. Part I: Intolerance of PainCart tests or tolerance at > 80% of maximum input intensity for any pain test for cold.
6. Part III: Intolerance of PainCart tests or tolerance at > 80% of maximum input intensity for any pain test for cold, pressure and electrical tests at the screening visit
7. Any confirmed significant allergic reactions (urticaria or anaphylaxis) against any drug, or multiple drug allergies(non-active hay fever is acceptable).
8. Intake of any medication that could affect the outcome of the study, as judged by the investigator, within 2 weeks before the first study treatment administration (1 month for enzyme inducing drugs like rifampicin orcarbamazepin), 4 weeks for live vaccines and 2 weeks for other vaccines including COVID-19 vaccines.
9. A history of alcoholism or current excess alcohol intake (including regular consumption of more than 2 units daily on average [1 unit = approximately 250 ml of beer, 100 ml of wine, or 35 m of spirits]); inability to refrain from the intake of alcohol from 48 h before the first study treatment administration and during the stay at the study centre.
10. Use of nicotine-containing products within 3 months before screening.
11. Inability to refrain from using nicotine-containing products during the stay at the study centre.
12. History of drug abuse within 2 years or positive drug screen at screening.
13. Inability to refrain from methylxanthine-containing beverages or food (coffee, tea, cola, chocolate, energy drinks) from 48 hours (2 days) before the admission and during the stay at the study centre.
14. Blood donation or loss of significant amount of blood (≥ 500 ml) within 3 months before the admission to study centre.
15. Abnormal 12-lead ECG finding of clinical relevance at the screening visit, (after 5 min rest in supine position, confirmed by a repeat measurement) for example:
15.1. QT c (calculated through the Fridericia's formula) > 450 msec for male and > 470 msec for female subjects (If QTcinterval measured by the ECG machine algorithm is > 450/470 ms, 2 additional recordings will be done and mean QTcF value used to determine eligibility)
15.2. PR < 120 msec or > 200 msec
15.3. QRS < 70 msec or > 120 msec
15.4. 2° or 3° AV block
15.5. ventricular tachycardia
16. HR < 45 bpm or > 100 bpm after 5-minute supine rest at the screening visit. 3 recordings will be taken at 2 minute intervals and the mean value will be used to determine eligibility.
17. At the screening visit (3 recordings will be taken at 2 minute intervals and the mean value will be used to determine eligibility):• SBP < 90 mmHg or > 139 mmHg after 5 min in supine position• DBP < 45 mmHg or > 89 mmHg after 5 min in supine position• orthostatic hypotension after 2 minutes in standing position:i. decrease of 20 mmHg for SBPii. decrease of 10 mmHg for DBP
18. Positive serology to human immunodeficiency virus (HIV) antibodies, hepatitis B surface antigen (HBs) or hepatitis C virus (HCV) antibodies at screening.
19. Positive test for COVID-19 on Day -1 or within 7 days prior to screening, or before the first study treatment administration.
20. Any abnormal value of laboratory, vital signs, or physical examination, which may in the opinion of the investigator interfere with the interpretation of the test results or cause a health risk for the subject if he/she takes part into the study.
21. Pregnant or lactating females.
22. Positive answer to item 4 or 5 on the Colombia-Suicide Severity Rating Scale (C-SSRS) or current risk of suicide based on the investigator's judgement.
23. Participation in an investigational drug study within 3 months before the first study treatment administration.

24. Any condition requiring regular concomitant treatment including herbal products and vitamins or likely to need any concomitant treatment during the study. As an exception paracetamol for occasional headache and another pain is allowed. Also hormonal contraception and hormone replacement therapy are allowed.

Date of first enrolment
24/08/2022

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Centre for Human Drug Research
Zernikedreef 8
Leiden
Netherlands
2333 CL

Sponsor information

Organisation
Orion Corporation (Finland)

ROR
https://ror.org/0296s4x19

Funder(s)

Funder type
Industry

Funder Name
Orion Corporation

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes