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Tetrodotoxin and quantitative sensory testing in healthy volunteers

Submission date	Recruitment status	[ ] Prospectively registered
18/08/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/09/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/09/2023	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This research is a type of medical study which is in the second stage of testing. The main goal is to understand how a substance called Halneuron (also known as tetrodotoxin) affects the nerves in the peripheral nervous system in the body. The researchers will use a special test called Quantitative Sensory Testing (QST) to measure these effects. The information learned from this study will help create a detailed set of tests that can be used to check the analgesic efficacy in patients who experience pain.

Who can participate?
Healthy volunteers aged between 18 and 55 years old

What does the study involve?
Participants will be administered two doses of Halneuron (tetrodotoxin) subcutaneously.

What are the possible benefits and risks of participating?
The benefit of this study outweighs the risks for individual subjects and the clinical study as a whole. Halneuron has already been tested at the intended doses in clinical studies in healthy subjects without serious or severe adverse events.

Where is the study run from?
Leiden University Medical Center (LUMC) (The Netherlands)

When is the study starting and how long is it expected to run for?
March 2022 to March 2024

Who is funding the study?
WEX Pharmaceuticals Inc (Canada)

Who is the main contact?
Kiki Kuijpers, k.w.k.kuijpers@lumc.nl (The Netherlands)

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2022-500318-24-00

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of quantitative sensory testing (QST) Using subcutaneous administration of single escalating doses of Halneuron® (tetrodotoxin (TTX) for injection) in healthy volunteers

Acronym
TETRO

Study objectives
The study aims to develop a sensitive test battery that can be applied to assess analgesic efficacy in pain patients

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/07/2023, Medical Ethics Review Committee Leiden The Hague Delft (Albinusdreef 2, Leiden, 2333ZA, Netherlands; +31(0)715263241; metc-ldd@lumc.nl), ref: P23.048

Study design
Single-centre single-escalating-dose study

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
In this study, two doses of Halneuron (tetrodotoxin) will be administered subcutaneously. During this study, there will be no randomization.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Tetrodotoxin

Primary outcome(s)

Sensation and pain thresholds measured using Quantitative Sensory Testing (QST) after two different doses of Halneuron (Tetrodotoxin (TTX) for Injection)

Key secondary outcome(s))
None provided

Completion date
01/03/2024

Eligibility

Key inclusion criteria
1. Aged 18 to 55 years old (inclusive)
2. Body mass index (BMI) within 19-30 kg/m2
3. Subjects will be healthy according to physical examination (including vital signs) and normal laboratory tests (hematology, biochemistry, urinalysis) including, as well as a negative screening of ethyl alcohol and drugs of abuse in urine.

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
Not meeting the participant inclusion criteria

Date of first enrolment
01/09/2023

Date of final enrolment
01/02/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center (LUMC)
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Sponsor information

Organisation
Leiden University Medical Center

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Industry

Funder Name
WEX Pharmaceuticals Inc

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the confidentiality of these data.

IPD sharing plan summary
Not expected to be made available