

Tetrodotoxin and quantitative sensory testing in healthy volunteers

Submission date 18/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/09/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/09/2023	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Type(s)

Public

Contact name

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

2022-500318-24-00

ClinicalTrials.gov (NCT)

Nil known

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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233 ZA

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