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A multicentre, randomized, double-blind, placebo-controlled, parallel-design trial of the efficacy and safety of subcutaneous tetrodotoxin (Tectin) for moderate to severe inadequately controlled cancer-related pain

Submission date
17/10/2005

Recruitment status
No longer recruiting

Registration date
07/11/2005

Overall study status
Completed

Last Edited
12/01/2021

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WEX-014

Study information

Scientific Title
A multicentre, randomized, double-blind, placebo-controlled, parallel-design trial of the efficacy and safety of subcutaneous tetrodotoxin (Tectin) for moderate to severe inadequately controlled cancer-related pain

Acronym
TTX

Study objectives
To determine whether subcutaneous tetrodotoxin is more effective than placebo in reducing the intensity of cancer-related pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
A multicentre, randomized, double-blind, placebo-controlled, parallel-design trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer- and cancer therapy-related pain

Interventions
Subcutaneous tetrodotoxin versus placebo

Intervention Type
Drug

Phase

Not Specified

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

Primary outcome measure
Changes in pain intensity compared to baseline

Secondary outcome measures
1. Onset, peak, and duration of pain intensity reduction
2. Changes in the impact of pain on emotional and physical function compared to baseline

Overall study start date
30/12/2003

Completion date
31/03/2006

Eligibility

Key inclusion criteria
1. Male or female 18 years of age and over
2. In-patients or out-patients with a diagnosis of cancer
3. Stable but inadequately controlled pain with current therapy for at least two weeks
4. Patients must be experiencing somatic, visceral and/or neuropathic pain related to cancer
5. Pain intensity, assessed by Question #3 of the Brief Pain Inventory (BPI short form) meets the definition of 'moderate' (score of 4-5) or 'severe' (score of 6-10) pain
6. Life expectancy of >3 months
7. Ability to communicate well with the Investigator and to comply with the requirements of the entire study
8. Willingness to give written informed consent (prior to any study-related procedures being performed) and to be able to adhere to the study restrictions, appointments, and examination schedule

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
146

Total final enrolment

Key exclusion criteria
1. Planned initiation of chemotherapy, radiotherapy, or bisphosphonates within 30 days prior to randomization
2. Use of anaesthetics
3. Use of lidocaine and other types of antiarrhythmic drugs
4. Use of scopolamine and acetylcholinesterase-inhibiting drugs such as physostigmine
5. History of CO2 retention, or SaO2 <90% either on room air or O2 of not greater than 2-4 l/min by nasal cannula
6. Second or third degree heart block or prolonged QTc interval (corrected for rate) on screening electrocardiogram(ECG) (confirmed >450 msec on repeated occasion) or any other active cardiac arrhythmia or abnormality that could constitute a clinical risk
7. Coagulation or bleeding defects if in the opinion of the Investigator this represents a risk to the subject considering the subcutaneous (sc) route of administration
8. Known hypersensitivity to puffer fish, tetrodotoxin and/or its derivatives
9. Received an investigational agent within 30 days prior to screening or who is scheduled to receive an investigational drug other than tetrodotoxin during the course of the study
10. Previous use of tetrodotoxin
11. Females who are lactating or at risk of pregnancy (i.e. sexually active with fertile males and not using an adequate form of birth control)
12. Females with a positive serum pregnancy test at screening or positive urine pregnancy test on admission to study site
13. Any other condition that, in the opinion of the investigators, is likely to interfere with the successful collection of the measures required for the study or poses a risk to the patient

Date of first enrolment
30/12/2003

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
Canada

Study participating centre
Medical Oncology
Calgary, Alberta
Canada
T2N 4N2

Sponsor information

Organisation

Wex Pharmaceuticals Inc (Canada)

Sponsor details
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Sponsor type
Industry

Website
http://www.wexpharma.com

Funder(s)

Funder type
Industry

Funder Name
Wex Pharmaceuticals Inc

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2008	12/01/2021	Yes	No