TCTR ID : TCTR20211220008

OTHER ID :

Overall Recruitment Status : Pending (Not yet recruiting)

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date :	20 December 2021
First Posted Date :	20 December 2021
Last Update Posted Date :	20 December 2021

Title

Public Title :	Effectiveness and safety of transdermal medical cannabis (THC:CBD formulas) to treatment painful diabetic peripheral neuropathy of the Lower Extremities
Acronym :	Painful-DPN/THC:CBD
Scientific Title :	A Phase 3 Enriched Enrollment Randomized Withdrawal Study to investigate Analgesic Efficacy and Safety of Transdermal medical cannabis (THC: CBD formulas) in Subjects With Painful Diabetic Peripheral Neuropathy
Sponsor ID/ IRB ID/ EC ID :	HE641352
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20211220008
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	HE641352
Date of Approval :	20 August 2021
Board Name :	Office of the Khon Kaen University Ethics Committee in Human Research
Board Affiliation :	Khon Kaen University Ethics Committee for Human Research, Panel 1
Board Contact :	Business Phone : 0897141913 Ext. No Data Business Email : eckku@kku.ac.th Business Address : Wadwichakarn Building , 3 rd Floor, Room 5317 Faculty of Medicine, Khon Kaen University, 40002 Thailand

Sponsor

Source(s) of Monetary or Material Supports :	Herb and Thai Traditional Medicine Development Division, Department of Thai Traditional and Alternative Medicine, Ministry Of Public Health
Study Primary Sponsor :	Faculty of Medicine, Khon Kaen University
Responsible Party :	Name/Official Title : Department of Community Medicine, Faculty of Medicine Organization : Khon Kaen University Phone : 043363588 Ext. No Data Email : pattapng@kku.ac.th
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	The study is designed to investigate the benefit of transdermal medical cannabis (THC: CBD formulas) to treat painful diabetic peripheral neuropathy of the Lower Extremities. The purpose of this study is to assess the effectiveness and safety of 12- week transdermal medical cannabis (THC: CBD formulas) in diabetic patients with painful diabetic peripheral neuropathy of the lower extremities. Effectiveness will be assessed in terms of the changes in the average neuropathic pain intensity scores. Safety will be assessed using standard tools.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Type II Diabetic Mellitus Neuropathic Pain Painful Diabetic Peripheral Neuropathy (PDPN)
Keywords :	Peripheral Nervous System Diseases Neuralgia Neuralgia Pain Neuromuscular Diseases Nervous System

Diseases Neurologic Manifestations Diabetes Complications Diabetes Mellitus Endocrine System Diseases

Eligibility

Inclusion Criteria :
1. Established diagnosis of diabetes II with painful diabetic peripheral neuropathy and glycosylated haemoglobin, HbA1c less than 11% at screening.
2. Stable glycemic control, HbA1c less than 11% achieved by a drug regimen for at least three months prior to screening.
3. At least a 1-year history of painful diabetic peripheral neuropathy.
4. Subjects must be over 20 years of age, Male and Female.
5. Subjects had painful diabetic peripheral neuropathy as measured using the Neuropathic Pain Symptom Inventory (NPSI) criteria.
6. The subjects were undergoing treatment under the supervision of a physician. They were treated with hypoglycemic drugs and had stable disease symptoms at least 12 weeks before the start of the study.
7. Subjects had painful diabetic peripheral neuropathy who had severity ranging from mild, moderate, and severe.
8. The Subjects did not use other drugs that affect pain caused by diabetic neuropathy.
9. Who had been treated for peripheral neuropathy but were unsuccessful with other treatments.
10. The Subjects were treated not inferior to standard care. Who was able to adjust the dose as appropriate in the amount that could treat the sciatic nerve pain and must tell the number of doses used so that the researchers can record and use the results to evaluate the product's effectiveness.
11. Subjects can listen to clarifications on the practice of medical cannabis use. Have an understanding of the clinical trial process, Cooperation in attending physical examinations by appointment, and the clinical trial process according to the practice guidelines of the trial until the completion of the process.
12. Subjects can provide information. Furthermore, express consent to clinical trials by voluntary written consent as a volunteer at the beginning of the trial.

Gender : Both

Age Limit : Minimum : 20 Years Maximum : N/A (No limit)

Exclusion Criteria :
1. Cerebrovascular events or other neurological illnesses in the past.
2. Subjects with other pathological conditions including cirrhosis, hepatitis, Hepatic carcinoma, cancer, HIV, AIDS, CKD end-stage.
3. Serious illnesses were precluding the gathering of or potentially impacting primary and secondary outcome measures, for example, major organ failure, neoplasia, or coeliac disease.
4. The subjects used various forms of medicinal cannabis products at least three months prior to the trial. They did not stop using medical cannabis prior to the study: Moreover, they were known or suspected hypersensitivity to cannabinoids or any of the excipients of the study medications.
5. Subjects treated with antidepressants, Tricyclic antidepressants, serotonin-norepinephrine reuptake inhibitors (SNRIs), calcium channel blockers, opioids, Tramadol, and other drugs that affect nerve pain such as Capsaicin cream, Lidocaine cream, or patch before the start of the trial and had stopped taking the drugs at least 3 months before the start of the study.
6. Subjects who received anti-seizure drugs and other drugs that reduce nerve pain. before the start of the study and had stopped taking the drug at least three months before the start of the study.
7. Subjects who have been planning surgery are Currently undergoing rehabilitation after neurosurgery to treat herniated disc pain.
8. Subjects with nerve damage caused by other causes such as cancer, central nervous system accidents. and peripheral nervous system.
9. After entering a research study, subjects do not voluntarily continue to volunteer for the duration of the study.
10. Subjects with a medical history and family history of psychiatric disorders such as schizophrenia, bipolar disorder, chronic depression, suicidal ideation, and psychosis.
11. Current or history of substance abuse.
12. Subjects who underwent medical examinations were discovered to have physical abnormalities such as deformities, diabetic foot ulcers, or other abnormalities that the medical practitioner determined prevented them from participating in the research to assure the sample group's safety.
13. Subjects who had an amputation due to diabetic nerve injury before enrolling in the trial.
14. During the trial, women who were pregnant, breastfeeding, or planned to become pregnant were excluded.
15. Subjects who intend to go beyond the area or who were not in the area throughout the 12-week research period.
16. The patient's cognitive impairment is severe enough that he or she cannot give informed consent.
17. Subjects are suspected or confirmed patients of coronavirus 2019 infection who'll be investigated and monitored for the spread of the disease for 14-21 days.
18. Subjects are undergoing other research studies treated or treated for diabetic peripheral neuropathy.

Accept Healthy Volunteers : No

Status

Overall Recruitment Status :	Pending (Not yet recruiting)	
Key Trial Dates	Study Start Date (First enrollment) : 01 February 2022	Indicate Type : Anticipated
	Completion Date (Last subject, Last visit) : 30 April 2022	Indicate Type : Anticipated
	Study Completion Date : 30 April 2022	Indicate Type : Anticipated

Design

Study Type :	Interventional
Primary Purpose :	Treatment
Study Phase :	Phase 3
Intervention Model :	Parallel
Number of Arms :	2
Masking :	Masked Masked Role : Allocation concealment, Subject, Caregiver, Investigator, Outcome Assessor, Statistician
Allocation :	Randomized
Control :	Placebo
Study Endpoint Classification :	Safety/Efficacy Study
Sample size	
	Planned sample size : 100
Intervantion Arm 1	
	Intervention name : Transdermal medical cannabis (THC: CBD formulas)
	Intervention Type : Active Comparator
	Intervention Classification : Drug
	Intervention Description : Drug: transdermal medical cannabis (THC:CBD formulas)
Intervantion Arm 2	
	Intervention name : Placebo (Coconut oil extract)
	Intervention Type : Placebo Comparator
	Intervention Classification : Drug
	Intervention Description : Drug: Placebo (Coconut oil extract)

Outcome

Primary Outcome

1. Outcome Name :	average pain intensity
Metric / Method of measurement :	Neuropathic Pain Symptom Inventory (NPSI)
Time point :	From Screening (Baseline data Day 0) and 24 hrs post-dose and at 4, 8, 12 weeks to End of Study Visit (12 weeks
2. Outcome Name :	pain symptoms
Metric / Method of measurement :	Neuropathic Pain Symptom Inventory (NPSI)
Time point :	From Screening (Baseline data Day 0) and 24 hrs post-dose and at 4, 8, 12 weeks to End of Study Visit (12 weeks

Secondary Outcome

1. Outcome Name :	safety, tolerability and side effect
Metric / Method of measurement :	Grading Dermatologic Adverse Events in Clinical Trials Using CTCAE v4.0 and HPVC Form 1.
Time point :	From Screening (Baseline data Day 0) and 24 hrs post-dose and at 4, 8, 12 weeks to End of Study Visit (12 weeks
2. Outcome Name :	Quality of life
Metric / Method of measurement :	Health-related quality of life measure (EQ-5D-5L)
Time point :	From Screening (Baseline data Day 0) and 24 hrs post-dose and at 4, 8, 12 weeks to End of Study Visit (12 weeks
3. Outcome Name :	neurophysiology
Metric / Method of measurement :	sensory and motor nerve function to the lower limbs.
Time point :	From Screening (Baseline data Day 0) and 24 hrs post-dose and at 4, 8, 12 weeks to End of Study Visit (12 weeks

4. Outcome Name : Intention-to-treat analysis

Metric / Method of measurement : Responder rate

Time point : From Screening (Baseline data Day 0) and 24 hrs post-dose and at 4, 8, 12 weeks to End of Study Visit (12 weeks

Location

Section A : Central Contact

Central Contact	First Name : Khachornsak	Middle Name :	Last Name : Seevathee
	Degree :	Phone : 0956549528 Ext. : No Data	Email : khachornsak@kkumail.com
Central Contact Backup	First Name : Pattapong	Middle Name :	Lastname : Kessomboon
	Degree : Associate Professor	Phone : 0831456437 Ext. : No Data	Email : pattapng@kku.ac.th

Section B Facility Information and Contact

1. Site Name : Donchan hospital, Kalasin Provincial Public Health Office, Ministry Of Public Health, Thailand

	City : Donchan district	State/Province : Kalasin Province	Postal Code : 46000
	Country : Thailand	Recruitment Status : Pending (Not yet recruiting)	
Facility Contact	First Name : Khachornsak	Middle Name :	Last Name : Seevathee
	Degree :	Phone : 0956549528 Ext. : No Data	Email : khachornsak@kkumail.com
Facility Contact Backup	First Name : Pattapong	Middle Name :	Last Name : Kessomboon
	Degree : Associate Professor	Phone : 0831456437 Ext. : No Data	Email : pattapng@kku.ac.th
Investigator Name	First Name : Khachornsak	Middle Name :	Last Name : Seevathee
	Degree : PhD.candidates	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Khachornsak	Middle Name :	Last Name : Seevathee
Degree : No Data	Phone : 0956549528 Ext. : No Data	Email : khachornsak@kkumail.com
Postal Address : 128/6 Donchan hospital, Kalasin Provincial Public Health Office, Ministry Of Public Health, Thailand		
State/Province : Kalasin	Postal Code : 46000	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Donchan hospital, Kalasin Provincial Public Health Office, Ministry Of Public Health, Thailand		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Suyan	Middle Name :	Last Name : Luangphimai
Degree : MD.	Phone : 0855144941 Ext. : No Data	Email : gosolo18@hotmail.com
Postal Address : 128/6 Donchan hospital, Kalasin Provincial Public Health Office, Ministry Of Public Health, Thailand		
State/Province : Kalasin	Postal Code : 46000	
Country : Thailand	Official Role : Study Chair	
Organization Affiliation : Donchan hospital, Kalasin Provincial Public Health Office, Ministry Of Public Health, Thailand		

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No

Reason : Health status information and treatment are kept confidential.

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data