

TCTR ID : TCTR20220622002

Overall Recruitment Status : Unknown

OTHER ID :

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

Tracking Information

First Submitted Date : 20 June 2022
First Posted Date : 22 June 2022
Last Update Posted Date : 22 June 2022

Title

Public Title : Efficacy and Safety of Cannabidiol Oil in Psoriasis: A Randomized, Double-Blind, Placebo-Controlled Trial
Acronym : No Data
Scientific Title : Efficacy and Safety of Cannabidiol Oil in Psoriasis: A Randomized, Double-Blind, Placebo-Controlled Trial
Sponsor ID/ IRB ID/ EC ID : N35A650697, COA 092/2565
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20220622002>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : COA092/2565
Date of Approval : 24 April 2022
Board Name : INSTITUTIONAL REVIEW BOARD FACULTY OF MEDICINE VAJIRA HOSPITAL
Board Affiliation : Navamindradhiraj University, Bangkok, Thailand
Board Contact : Business Phone : 022443843 Ext. No Data
Business Email : ec.adisorn@gmail.com
Business Address : 681 SAMSEN ROAD, DUSIT, BANGKOK 10300

Sponsor

Source(s) of Monetary or Material Supports : National Research Council of Thailand (NRCT)
Study Primary Sponsor : National Research Council of Thailand (NRCT)
Responsible Party : Name/Official Title : Assoc. Prof. Wanjarus Roongpisuthipong
Organization : Vajira Hospital, Navamindradhiraj University
Phone : 022443000 Ext. 3461
Email : wanjarus@nmu.ac.th
Study Secondary Sponsor : No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis : Objective: To study efficacy and safety of Cannabidiol Oil in Psoriasis:
Study design: A Randomized, Double-Blind, Placebo-Controlled Trial

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Psoriasis
Keywords : Psoriasis, Chronic plaque type psoriasis

Eligibility

Inclusion Criteria : - Chronic plaque type psoriasis patients
- Age 18-80 years old
- No change of systemic treatment with in last 1 month
Gender : Both
Age Limit : Minimum : 18 Years Maximum : 80 Years
Exclusion Criteria : - Current biologic therapy

- Active psychiatric problem with in last 1 year
- Active hepatic or renal diseases
- Pregnancy or lactation
- Allergy to cannabidiol (CBD) or CBD derivatives

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Unknown

Key Trial Dates	Study Start Date (First enrollment) : 01 July 2022	Indicate Type : Anticipated
	Completion Date (Last subject, Last visit) : 30 June 2023	Indicate Type : Anticipated
	Study Completion Date : 30 June 2023	Indicate Type : Anticipated

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 2

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 : 28

Intervention Arm 1

Intervention name : cannabidiol (CBD)

Intervention Type : Active Comparator

Intervention Classification : Drug

Intervention Description : cannabidiol (CBD) dose 30 mg per dose, 0.3 ml, per oral, twice a day, total duration of 12 weeks

Intervention Arm 2

Intervention name : Placebo

Intervention Type : Placebo Comparator

Intervention Classification : Dietary Supplement

Intervention Description : Placebo dose, 0.3 ml, per oral, twice a day, total duration of 12 weeks

Outcome

Primary Outcome

1. Outcome Name : Severity of psoriasis

Metric / Method of measurement : Psoriasis Area Severity index

Time point : at 12 weeks after end of the intervention

Secondary Outcome

1. Outcome Name : Itching

Metric / Method of measurement : visual analog scale of itch

Time point : at 12 weeks after end of the intervention

2. Outcome Name : Quality of life

Metric / Method of measurement : Dermatology Life Quality Index

Time point : at 12 weeks after end of the intervention

3. Outcome Name : Depression/anxiety/stress

Metric / Method of measurement : Depression anxiety stress scales

Time point : at 12 weeks after end of the intervention

4. Outcome Name : Sleep quality

Metric / Method of measurement : the Pittsburgh sleep quality index

Time point : at 12 weeks after end of the intervention

5. Outcome Name : Sleep efficiency

Metric / Method of measurement : Sleep efficiency percentage

Time point : at 12 weeks after end of the intervention

Location

Section A : Central Contact

Central Contact First Name : Wanjarus Middle Name : Last Name : Roongpisuthipong

Degree : MD Phone : 022443000 Ext. : No Data Email : wanjarus@nmu.ac.th

Central Contact Backup First Name : Theerawut Middle Name : Lastname : Klangjareonchai

Degree : MD Phone : 022003000 Ext. : No Data Email : theerawutklang@gmail.com

Section B Facility Information and Contact

1. Site Name : Vajira Hospital, Navamindradhiraj University

City : Dusit State/Province : Bangkok Postal Code : 10300

Country : Thailand Recruitment Status : Pending (Not yet recruiting)

Facility Contact First Name : Wanjarus Middle Name : Last Name : Roongpisuthipong

Degree : MD Phone : 022443000 Ext. : No Data Email : wanjarus@nmu.ac.th

Facility Contact Backup First Name : Theerawut Middle Name : Last Name : Klangjareonchai

Degree : MD Phone : 022003000 Ext. : No Data Email : theerawutklang@gmail.com

Investigator Name First Name : Wanjarus Middle Name : Last Name : Roongpisuthipong

Degree : MD Role : Principal Investigator

Section C : Contact for Public Queries (Responsible Person)

First Name : Wanjarus Middle Name : Last Name : Roongpisuthipong

Degree : MD Phone : 022443000 Ext. : No Data Email : wanjarus@nmu.ac.th

Postal Address : 681 Samsen road Dusit

State/Province : Bangkok Postal Code : 10300

Country : Thailand Official Role : Study Principal Investigator

Organization Affiliation : Navamindradhiraj university

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Theerawut Middle Name : Last Name : Klangjareonchai

Degree : MD Phone : 022003000 Ext. : No Data Email : theerawutklang@gmail.com

Postal Address : Somdej-phra-theeparat Building 270 Rama VI RD

State/Province : Bangkok Postal Code : 10400

Country : Thailand Official Role : Study Director

Organization Affiliation : Ramathibodi Hospital, Mahidol University

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No

Reason : Fear of inappropriate use of data and Need a consensus from colleagues

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data
