# TCTR ID : TCTR20200221001

# OTHER ID :

**Overall Recruitment Status** : Completed **(No Results)**

**Retrospective registration**
**This protocol was registered after enrollment of the first participant.**

**Tracking Information**

| | |
|---|---|
| First Submitted Date : | 19 February 2020 |
| First Posted Date : | 21 February 2020 |
| Last Update Posted Date : | 21 February 2020 |

**Title**

| | |
|---|---|
| Public Title : | Effect of topical Zingiber cassumunar on painful diabetic neuropathy : A double-blind controlled trial |
| Acronym : | No Data |
| Scientific Title : | Effect of topical Zingiber cassumunar on painful diabetic neuropathy : A double-blind controlled trial |
| Sponsor ID/ IRB ID/ EC ID : | |
| Registration Site : | Thai Clinical Trials Registry |
| URL : | https://www.thaiclinicaltrials.org/show/TCTR20200221001 |
| Secondary ID : | |

**Ethics Review**

| | |
|---|---|
| 1. Board Approval : | Submitted, approved |
| Approval Number : | KE61099 |
| Date of Approval : | No Data |
| Board Name : | Khon Kaen Hospital Institute Review Board in Human Research |
| Board Affiliation : | Khon Kaen Hospital |
| Board Contact : | Business Phone : 043-232555 Ext. 1602<br>Business Email : irbkkh@gmail.com<br>Business Address : Khon Kaen Hospital Institute Review Board in Human Research 54,56 khon kaen hospital srichant Rd ,Nai Muang, Muang Khon Kean, Khon Kean 40000 Thailand. |

**Sponsor**

| | |
|---|---|
| Source(s) of Monetary or Material Supports : | none |
| Study Primary Sponsor : | none |
| Responsible Party : | Name/Official Title : Department of Social Medicine<br>Organization : Khon Kaen Hospital<br>Phone : 043-232555 Ext. 3306<br>Email : jbudkaew@cpird.in.th |
| Study Secondary Sponsor : | none |

**Protocol Synopsis**

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|---|---|
| Protocol Synopsis : | A double-blind randomized clinical trial was conducted in patients who diagnosed painful diabetic neuropathy. All participants received an oral Gabapentin 300 mg, 1 tablet daily before bed as a standard regimen. The first group received the Plai balm 15%w/w to apply on their feet for 3 times a day and the controlled group (n=15) received the placebo balm to apply on their feet for 3 times a day. Pain score scales in the 1st, 2nd and 4th weeks were assessed as the main objective. In addition, patientsâ€™ quality of life after the treatment, and adverse events were collected as the secondary objectives. The means of pain scores before and after treatment in each group and between groups were analyzed.<br>Results<br>There were 31 patients participated in this study. Sixteen patients were randomly assigned to receive an intervention, Plai, while 15-patient receive placebo. At the end of week 2 and week 4, a Plai group showed statistically significant lesser mean pain score than the placebo group (-1.47 95%CI: -1.96 to -1.30 p-value<br>Conclusion<br>Plai Balm has an efficacy in reducing pain in patients with painful diabetic neuropathy compared to placebo. |

**URL not available**

**Health Conditions**

Health Condition(s) or Problem(s) Studied : -pain score of painful diabetic neuropathy

Keywords : -Painful diabetic neuropathy -Plai balm.

**Eligibility**

Inclusion Criteria : Criteria included aged of 20-60 years who has been diagnosed with diabetic mellitus for 1 year at least, and had been tested for HbA1c within 6 months, patients who had suffered from pain intensity on scale as moderate (Numerical rating scale (NRS), Pain score â‰¥ 4), the defined positive monofilament score result.

Gender : Both

Age Limit : Minimum : 20 Years Maximum : 60 Years

Exclusion Criteria : Patient who has been diagnosed with diabetic mellitus less than one year, with other caused neuropathy, clinically significant cardiovascular, foot ulcer or/and infection, pregnancy and lactation, and allergic of Plai, were excluded.

Accept Healthy Volunteers : No

**Status**

Overall Recruitment Status : Completed

| | | |
|---|---|---|
| Key Trial Dates | Study Start Date (First enrollment) : 01 February 2019 | Indicate Type : Actual |
| | Completion Date (Last subject, Last visit) : 15 February 2019 | Indicate Type : Actual |
| | Study Completion Date : 01 March 2019 | Indicate Type : Actual |

**Design**

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : N/A

Intervention Model : Parallel

Number of Arms : 2

Masking : Double Blind

Allocation : Randomized

Control : Placebo

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size :

Actual sample size at study completion : 35

Intervantion Arm 1

Intervention name : plai balm 15%w/w

Intervention Type : Active Comparator

Intervention Classification : Drug

Intervention Description : plai balm 15%w/w apply 3 times/day and received gabapentin 300 mg once a day before bedtime

Intervantion Arm 2

Intervention name : placebo balm

Intervention Type : Placebo Comparator

Intervention Classification : Drug

Intervention Description : placebo balm apply 3 times/day and received gabapentin 300 mg once a day before bedtime

**Outcome**

**Primary Outcome**

**1**. Outcome Name : the mean change of pain scores

Metric / Method of measurement : numerical rating scale

Time point : 2 weeks

**Secondary Outcome**

**1**. Outcome Name : 50% reduction of pain
Metric / Method of measurement : numerical rating scale
Time point : 4 weeks

**Location**

**Section A : Central Contact**

| | | | |
|---|---|---|---|
| Central Contact | First Name : NACHAPOL | Middle Name : | Last Name : JATUTEN |
| | Degree : MD | Phone : 0895779664 Ext. : No Data | Email : jatuten.n@gmail.com |
| Central Contact Backup | First Name : Paungtong | Middle Name : | Lastname : piyakunmala |
| | Degree : MD | Phone : 0817603533 Ext. : No Data | Email : p.piyakunmala@gmail.com |

**Section B Facility Information and Contact**

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|---|---|---|---|
| 1. | Site Name : selaphum Hospital | | |
| | City : selaphum | State/Province : roi-et | Postal Code : 45120 |
| | Country : Thailand | Recruitment Status : Completed | |
| **Facility Contact** | First Name : nachapol | Middle Name : | Last Name : jatuten |
| | Degree : MD | Phone : 0895779664 Ext. : No Data | Email : jatuten.n@gmail.com |
| **Facility Contact Backup** | First Name : lalipat | Middle Name : | Last Name : thiratanyaboon |
| | Degree : MD | Phone : 0897924597 Ext. : No Data | Email : lalipatthiratanyaboon@gmail.com |
| **Investigator Name** | First Name : | Middle Name : | Last Name : |
| | Degree : | Role : | |

**Section C : Contact for Public Queries (Responsible Person)**

| | | |
|---|---|---|
| First Name : NACHAPOL | Middle Name : | Last Name : JATUTEN |
| Degree : MD | Phone : 0895779664 Ext. : No Data | Email : jatuten.n@gmail.com |
| Postal Address : 244/12 nongyai, phontong | | |
| State/Province : roi-et | Postal Code : 45110 | |
| Country : Thailand | Official Role : Study Director | |
| Organization Affiliation : selaphum hospital | | |

**Section D : Contact for Scientific Queries (Responsible Person)**

| | | |
|---|---|---|
| First Name : sukanya | Middle Name : | Last Name : srisanthor |
| Degree : MD | Phone : 0988325415 Ext. : No Data | Email : look_chup@hotmail.com |
| Postal Address : selaphum hospital,selaphum | | |
| State/Province : roi-et | Postal Code : 45120 | |
| Country : Thailand | Official Role : Study Principal Investigator | |
| Organization Affiliation : selaphum hospital | | |

**Deidentified Individual Participant-level Data Sharing**

Plan to share IPD : No Data
Plan description : No Data

**Publication from this study**

MEDLINE Identifier : No Data
URL link to full text publication : No Data