TCTR ID: TCTR20220809007 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: 07 August 2022 First Posted Date: 09 August 2022 Last Update Posted Date: 09 August 2022

Title

Public Title: Acheta domesticus: A Natural Source of Antioxidant, Anti-Aging, and Anti-Inflammatory Active

Ingredients for Cosmetic Applications

Acronym: No Data

Scientific Title: Acheta domesticus: A Natural Source of Antioxidant, Anti-Aging, and Anti-Inflammatory Active

Ingredients for Cosmetic Applications

Sponsor ID/ IRB ID/ EC ID: AMSEC-64EX-029

Registration Site: Thai Clinical Trials Registry

URL: https://www.thaiclinicaltrials.org/show/TCTR20220809007

Secondary ID: No Secondary ID

Ethics Review

Board Approval: Submitted, approved
 Approval Number: AMSEC-64EX-029
 Date of Approval: 12 July 2022

Board Name: Human Research Ethics Unit Faculty of Associated Medical Sciences

Board Affiliation: Chiang Mai University, Thailand

Board Contact: Business Phone: 053936026 Ext. No Data

Business Email: research-ams@cmu.ac.th

Business Address: Faculty of Associated Medical Sciences, CMU, 110 Intawaroros Rd., Sripoom, Chiang

Mai, Thailand 50200

Sponsor

Source(s) of Monetary or Material Supports: Royal Golden Jubilee Ph.D. Program (RGJ-Ph.D. Program)

Study Primary Sponsor: Royal Golden Jubilee Ph.D. Program (RGJ-Ph.D. Program)

 $Responsible\ Party:\ Name/Official\ Title: Kankanit\ Yeerong$

Organization: Faculty of Pharmacy, Chiang Mai University

Phone: 0955989805 Ext. No Data Email: kankanit.yr@gmail.com

Study Secondary Sponsor: National Research Council of Thailand (NRCT)

Protocol Synopsis

Protocol Synopsis: To investigate cytotoxicity of Acheta domesticus extract on peripheral blood mononuclear cells (PBMCs)

using 3-[4,5-dimethylthiazol-2-yl]-2,5 diphenyl tetrazolium bromide (MTT) assay.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied: Five healthy volunteers (1 man and 4 women), aged between 18-59 years, were included in the study.

Keywords: Healthy volunteers

Eligibility

Inclusion Criteria: Five healthy volunteers (1 man and 4 women), aged between 18-50 years, were included in the study.

Gender: Both

Age Limit: Minimum: 18 Years Maximum: 50 Years

Exclusion Criteria: Having medical conditions

Accept Healthy Volunteers: Yes

Status

Overall Recruitment Status: Completed

Key Trial Dates Study Start Date (First enrollment) : 11 July 2022 Indicate Type : Actual

Study Completion Date: 10 July 2023 Indicate Type: Anticipated

Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: Phase 0
Intervention Model: Single arm

Number of Arms: 1

Masking: Masked Masked Role: Allocation concealment,

Allocation: N/A
Control: N/A

Study Endpoint Classification: Safety Study

Sample size

Planned sample size: 5

Actual sample size at study completion: 5

Intervantion Arm 1

Intervention name: Acheta domesticus extracts

Intervention Type : Experimental Intervention Classification : Other

Intervention Description: Cytotoxic effects of A. domesticus extracts on PBMCs using MTT assay. Five healthy volunteers one man and four women aged between twenty-one to fifty years were included in the study. Informed consent for study participation was obtained from all volunteers. PBMCs were collected from five blood donors. The blood was diluted with the same volume of PBS. Consequently, the diluted blood was added with Ficoll Paque reagent and then centrifuged. The PBMCs layer was collected and washed 3 times with PBS and cultured in RPMI 1640 media supplementing with ten percent FBS, one mM L glutamine, and one hundred microgram per ml penicillin streptomycin. PBMCs were separately added to each well of 96 well plates and incubated for 24 h in a humidified incubator. Consequently, each A. domesticus extract concentration ranging from 0 to 100 microgram/ml was added and further incubated for 48 h. After incubation the medium was discarded and MTT dye solution was added and further maintained for 4 h. Subsequently the supernatant was completely discarded. Then DMSO was added and mixed thoroughly to dissolve purple formazan crystals. The mixtures were measured for absorbance at 578 nm with a reference wavelength of 630 nm using an ELISA plate reader. The twenty percent of inhibitory concentration was defined as the concentration that can inhibit cell growth by twenty percent compared to the untreated cells.

Outcome

Primary Outcome

1. Outcome Name: Twenty percent of inhibitory concentration (IC20)

Metric / Method of measurement: MTT

Time point: 48 h

Secondary Outcome

1. Outcome Name: N/A
Metric / Method of measurement: N/A

Time point: N/A

Location

Section A: Central Contact

Central Contact First Name : Kankanit Middle Name : Last Name : Yeerong

Degree : Doctor of Pharmacy Phone : 0955989805 Ext. : No Data Email : kankanit.yr@gmail.com

Central Contact Backup First Name: Wantida Middle Name: Lastname: Chaiyana

Degree: Ph.D. Phone: 053944342 Ext.: No Data Email: Aa_Rx105@hotmail.com

Section B Facility Information and Contact

1. Site Name: Faculty of Associated Medical Sciences, Chiang Mai University

City: Mueang Chiang Mai State/Province: Chiang Mai Postal Code: 50200

Country: Thailand Recruitment Status: Completed

Facility Contact First Name : Kankanit Middle Name : Last Name : Yeerong

Degree : Doctor of Pharmacy Phone : 0955989805 Ext. : No Data Email : kankanit.yr@gmail.com

Facility Contact Backup First Name: Wantida Middle Name: Last Name: Chaiyana

Degree : Ph.D. Phone : 053944342 Ext. : No Data Email : Aa_Rx105@hotmail.com

Investigator Name First Name : Kankanit Middle Name : Last Name : Yeerong

Degree: Role: Principal Investigator

 $Section \ C: Contact \ for \ Public \ Queries \ (Responsible \ Person)$

First Name : Kankanit Middle Name : Last Name : Yeerong

Degree : Doctor of Pharmacy Phone : 0955989805 Ext. : No Data Email : kankanit.yr@gmail.com

Postal Address : 239 Suthep Alley, Mueang Chiang Mai Dist State/Province : Chiang Mai Postal Code : 50200

Country: Thailand Official Role: Study Principal Investigator

Organization Affiliation: Faculty of Pharmacy, Chiang Mai University

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Kankanit Middle Name : Last Name : Yeerong

Degree : No Data Phone : 0955989805 Ext. : No Data Email : kankanit.yr@gmail.com

Postal Address : 239 Suthep Alley, Mueang Chiang Mai Dist State/Province : Chiang Mai Postal Code : 50200

Country: Thailand Official Role: Study Principal Investigator

Organization Affiliation : Faculty of Pharmacy, Chiang Mai University

Summary Results

Date of posting of results summaries: Summary results not yet available

Date of first journal publication of results: Not yet published

Deidentified Individual Participant-level Data Sharing

Plan to share IPD: No

Reason: Need a consensus

Publication from this study

 $\label{eq:median} \mbox{MEDLINE Identifier}: \mbox{ No Data}$ $\mbox{URL link to full text publication}: \mbox{ No Data}$