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Comparative insect repellency study of combined lemongrass and peppermint oil lotion versus 25% DEET lotion against mosquitoes

Submission date
17/01/2024

Recruitment status
No longer recruiting

Registration date
09/02/2024

Overall study status
Completed

Last Edited
17/01/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dengue is a mosquito-borne viral infection endemic in the Philippines. One of the strategies advocated by the WHO to obtain protection from mosquitoes is the use of repellents. DEET-based repellents have been widely used but are known to cause adverse effects. This study tests an alternative and effective plant-based repellent. This study aims to compare the repellency action of lemongrass and peppermint oil lotion against DEET lotion against female Aedes aegypti mosquitoes.

Who can participate?
Healthy volunteers aged 18-40 years old

What does the study involve?
Participants were randomly allocated to one of two groups to have 5.0 grams of combined lemongrass and peppermint oil lotion or 5.0 grams of 25% DEET lotion applied from wrist to elbow. The repellent was dried before the arm was inserted into the cage containing 100 female mosquitoes, exposed for 3 minutes and observed for landing or probing. The procedure was repeated every hour for up to 6 hours. The occurrence of one landing and/or probing within 3 minutes indicates the end of complete protection time. Protection over time was determined using the same procedure from the treated versus untreated control arm.

What are the possible benefits and risks of participating?
This study involves moderate risks. Classification of combined lemongrass oil and peppermint oil lotion as non-irritant and safe will prompt the continuation of the study to the next phase. Possible adverse events range from mild symptoms, such as erythema (redness), itching, dryness, scaling or stinging; moderate symptoms such as burning, tenderness or pain; to severe symptoms such as formation of vesicles, erosions and/or crusting. However, no adverse events were noted throughout the study.

Where is the study run from?
Entomology Laboratory Standards and Testing Division, Industrial Technology Development Institute, Department of Science and Technology (Philippines)

When is the study starting and how long is it expected to run for?
January 2021 to October 2022

Who is funding the study?
1. League of Asean Dermatological Societies (LADS) (Philippines)
2. Philippine Dermatology Society (PDS) (Philippines)

Who is the main contact?
Dr Aira Monica R. Abella, aika2122001@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2021-17

Study information

Scientific Title

Comparative study of the insect repellency action of combined lemongrass oil and peppermint oil lotion versus 25% DEET (N,N-diethyl-meta-toluamide) lotion against female Aedes aegypti mosquitoes

Study objectives
There is a statistically significant difference in repellency between 25% DEET lotion and combined lemongrass oil and peppermint oil lotion based on the percentage protection against female Aedes aegypti mosquitoes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/08/2021, Institutional Review Board, Research Institute for Tropical Medicine (9002 Research Drive, Filinvest Corporate City, Alabang, Muntinlupa City, 1781, Philippines; +63 (0)632 88097599; irb@ritm.gov.ph), ref: 2021-17

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Laboratory

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Dengue

Interventions
Participants were randomized by simple randomization to one of two treatment groups. 5 grams of Repellent A - Combined Lemongrass and Peppermint oil lotion and 5 grams of Positive Control Repellent B - 25% DEET lotion were applied from wrist to elbow per treatment group. Repellent was dried before inserting into the cage containing 100 female mosquitoes, exposed for 3 minutes and observed for landing or probing. The procedure was repeated every hour up to 6 hours.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Phase 0

Drug/device/biological/vaccine name(s)
25% DEET (N,N-diethyl-meta-toluamide) lotion, combined lemongrass oil and peppermint oil lotion

Primary outcome measure
The % protection over time was determined by counting the number of mosquitoes landing /probing on the treated arm (T) in relation to the number of landings on the control untreated arm (C) of the same individual (% p = ((C-T)/C)) x 100) for a 3-minute exposure every hour (1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours).

Secondary outcome measures
Complete protection time was calculated as the number of minutes elapsed between the time of repellent application and the first mosquito landing or probing for a 3-minute exposure every hour (1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours).

Overall study start date
02/01/2021

Completion date
10/10/2022

Eligibility

Key inclusion criteria
1. Healthy male or female aged 18–40 years
2. Must know how to read and write
3. Must be willing to comply with the study protocol requirements
4. Must be willing to sign an informed consent after having clearly understood its content
5. Must be willing to have photos taken for documentation purposes during the experiment

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
46

Total final enrolment
46

Key exclusion criteria
1. Pregnant or lactating women
2. Those with a history of allergy or hypersensitivity reactions to insect repellents and its components
3. Those with a history of adverse reactions to insect bite
4. Those who have active skin lesions or other dermatological disorders (like atopic dermatitis, psoriasis)
5. Those with a history of other comorbid conditions (diabetes, hypertension, malignancy)
6. Current or ex-smoker (≥10 pack years)

Date of first enrolment
21/04/2022

Date of final enrolment
27/06/2022

Locations

Countries of recruitment
Philippines

Study participating centre
Entomology Section, Biological Laboratory, Standards and Testing Division, Department of Science and Technology - Industrial Technology Development Institute
DOST Compound, General Santos Avenue, Bicutan
Taguig City
Philippines
1631

Sponsor information

Organisation
Research Institute for Tropical Medicine

Sponsor details
Filinvest Marketing & Exhibit Office
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Sponsor type
Government

Website
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ROR
https://ror.org/01g79at26

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Philippine Dermatological Society

Funder Name
League of Asean Dermatological Societies

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Afterwards patent application and commercialization of product.

Intention to publish date
22/07/2024

Individual participant data (IPD) sharing plan
All raw data will be available including the participants' consent forms. Kindly contact the main author via email, Dr Aira Monica R. Abella (aika2122001@gmail.com). Other files can also be made available:

1. Raw data of results
2. Photographs of methods (ex: laboratory set-up, arm-in-cage procedure, plant materials, etc)
3. List of subject volunteer participants
4. Informed consent forms

All data can be shared immediately upon request. Consent from participants was obtained prior to the procedure.

IPD sharing plan summary

Available on request