

# Efficacy and safety of sun block in the management of acne and post acne pigmentation among Malaysian patients

<b>Submission date</b> 07/10/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/10/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/08/2024	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims:

Acne affects up to 85% of the adolescents, with 80% of cases may develop post acne pigmentation. Retinoids are effective, but intolerance is common, thus limiting their usage. Cosmeceuticals may improve tolerability of retinoids. We aim to explore the effectiveness and tolerability of a Lichochalcone A containing sunscreen in the management of acne and post acne pigmentation.

### Who can participate:

Adults, male and female, with mild to moderate acne vulgaris, complicating with post acne pigmentation are eligible to participate

### What does this study involve?

This is a randomized, double blinded, comparator-controlled trial will be conducting in the Universiti Putra Malaysia Teaching Hospital from March 2022 to June 2022. A 2-week walk-in period will be used to assess the efficacy and tolerability of adapalene. The subjects will then randomized into two arms, each receiving different sunscreen, to be used concurrently with adapalene. They will be followed up for another 4 weeks to observe for the improvement of acne severity, post acne hyperpigmentation index, melanin and erythema index and complication rates.

### What are the possible benefits and risks of participating?

#### (a) TO THE SUBJECT

You will be closely followed up according to the study protocol and get to be monitored closely for any potential intolerance to the treatment received. You will also be receiving a good quality sunscreen, which may or may not benefit your facial acne and pigmentation. You will get to have your skin assessed in a more objective manner, which rarely available during the usual clinic consult. During each followup, you will be assigned with a RM30 emolument to cover your travel expenses. Please be informed that tea/ lunch will be provided, depending on your visiting time.

**(b) TO THE INVESTIGATOR**

This study will allow the health care provider to understand the role of sunprotection and its active ingredients in acne and acne pigmentation management better.

Where is the study run from?

Universiti Putra Malaysia Teaching Hospital

When is the study starting and how long is it expected to run for?

October 2021 to July 2022

Who is funding the study?

This study will be funded by Beiersdorf (Malaysia) Sdn Bhd

Who is the main contact?

Dr Kang Nien How, hkangnien@upm.edu.my

## **Contact information**

**Type(s)**

Principal Investigator

**Contact name**

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## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

JKEUPM-2021-288 (NMRR-21-793-59045)

## **Study information**

**Scientific Title**

A comprehensive study of the efficacy and safety of Licochalcone A , Glycyrrhetic acid and L-Carnitine containing sun block in the management of acne and post acne pigmentation among Malaysian patients : A randomized, double blinded, comparator controlled trial

**Study objectives**

Licochalcone A, Glycyrrhetic acid and L-Carnitine containing sunscreen is effective in reducing acne and post acne hyperpigmentation.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 06/10/2021, Universiti Putra Malaysia Ethic Committee for Research Involving Human Subject (JKEUPM, Universiti Putra Malaysia, 43400 UPM Serdang, Selangor Darul Ehsan, Malaysia; +60 397691605; jkeupm@upm.edu.my), ref: UPM/TNCPI/RMC/JKEUPM/1.4.18.2

**Study design**

Randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

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

Improve the treatment of acne and acne pigmentation

**Interventions**

Walk in period using adapalene for 2 weeks, followed by randomization into intervention and control arm

Intervention: Licochalcone A containing sunscreen + Adapalene

Control arm: Comparator sunscreen + adapalene

Follow-up duration for intervention: 4 weeks

Total duration of study: 6 weeks

Randomization process: chit method - total 56 chits were divided into 2 groups, 28 each. Each chit was written "A" or "B". These chits are then put into a black box, not visible from the

outside. Participants were asked to draw from this box. They were randomized according to which chit they had drawn. A was into intervention, while B was into the control arm. Chits drawn will be discarded and will not be replaced.

### **Intervention Type**

Other

### **Primary outcome measure**

1. Acne severity using CASS at baseline and week 6
2. Post acne pigmentation using PAHPI at baseline and week 6

### **Secondary outcome measures**

At baseline and week 6:

1. Total number of inflammatory and non inflammatory acne
2. Acne severity using GAGS
3. Post acne pigmentation using skin analyser
4. Sebum using sebumeter
5. Skin pH using pH meter probe
6. Treatment related complications using a check list of anticipated complication, and subjects' own report
7. Weight of cleanser, tretinoin and sunblock – determine compliance: subjects were asked to bring back their cleanser, tretinoin and sunblock. The above will be weighted using a weighing machine up to 2 decimal point.
8. Patient satisfaction to treatment using visual analogue scale. Scale range from worse, no change, good, very good.
9. Acne related quality of life using CADI

### **Overall study start date**

06/10/2021

### **Completion date**

30/07/2022

## **Eligibility**

### **Key inclusion criteria**

1. Males and females with acne vulgaris aged  $\geq 18$  years old
2. Clinically diagnosed by dermatologist as acne vulgaris on the face with
  - 2.1. Inflammatory lesion (papules and pustules) of  $< 25$
  - 2.2. Non inflammatory lesions (open or close comedones) of  $< 50$
3. Patient must have post acne pigmentation with at least a PAHPI score of 6

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

56

**Total final enrolment**

50

**Key exclusion criteria**

1. Other forms of acne (acne conglobata, acne excoriata, acne rosacea, acne cosmetica, pomade acne, acne fulminans, acne keloidalis nuchae, acne chloracne, acne mechanica and acne medicamentosa)
2. Nodulocystic acne
3. CASS 4-5
4. On oral antibiotic for the last 1 months
5. On oral isotretinoin for the last 6 months
6. On topical antimicrobial or tretinoin for the last 2 weeks
7. Photosensitivity
8. If patient is currently pregnant or lactating
9. Other comorbidities that require any route of medication commencement (i.e hypertension, diabetes, dyslipidemia, bronchial asthma)
10. If there is any known allergy to the active ingredients in the preparation
11. Patients who have any other facial dermatoses
12. Patients who like outdoor activities and couldn't comply to sunprotection.

**Date of first enrolment**

01/03/2022

**Date of final enrolment**

30/06/2022

**Locations****Countries of recruitment**

Malaysia

**Study participating centre**

Universiti Putra Malaysia Teaching Hospital

Persiaran Mardi - Upm

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43400

**Sponsor information**

**Organisation**

Beiersdorf (Malaysia)

**Sponsor details**

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**Sponsor type**

Industry

**Funder(s)****Funder type**

Industry

**Funder Name**

Beiersdorf

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

Germany

**Results and Publications****Publication and dissemination plan**

Planned publication in a Q3 ISI indexed journal "Cosmetic"

**Intention to publish date**

30/10/2022

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		23/12/2023	06/08/2024	Yes	No