ISRCTN31328643 https://doi.org/10.1186/ISRCTN31328643

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

Submission date
07/10/2022

Recruitment status
No longer recruiting

Registration date
26/10/2022

Overall study status
Completed

Last Edited
06/08/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Dr Kang Nien How

ORCID ID
https://orcid.org/0000-0002-8032-9804

Contact details
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
Serdang
Malaysia
43400
03 9769 5601
hkangnien@upm.edu.my

Additional identifiers

Protocol serial number
JKEUPM-2021-288 (NMRR-21-793-59045)

Study information

Scientific Title
A comprehensive study of the efficacy and safety of Licochalcone A , Glycyrrhetinic 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, Glycyrrhetinic acid and L-Carnitine containing sunscreen is effective is 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

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

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: Lichochalcone A containing sunscreen + Adapalene
Control arm: Comparator sunscreen + adapalene
Follow-up duration for intevention: 4 weeks
Total duration of study: 6 weeks
Randomization process: chit method - total 56 chits were divided into 2 groups, 23 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(s)
1. Acne severity using CASS at baseline and week 6
2. Post acne pigmentation using PAHPI at baseline and week 6

Key secondary outcome(s)
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

Completion date
30/07/2022

Eligibility

Key inclusion criteria
1. Males and females with acne vulgaris aged ≥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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Other forms of acne (acne conglobata, acne excoriate, 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
Serdang
Malaysia
43400

Sponsor information

Organisation
Beiersdorf (Malaysia)

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

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?
Results article		23/12/2023	06/08/2024	Yes	No