Supplementary Data

Study record 42560

Generated: 10/10/2022 8:39:38
Editorial Status: Queries with trialist

Title and Additional Identifiers

Submission number
42560

ISRCTN

DOI

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

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

Acronym

EudraCT number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

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

Condition category
Skin and Connective Tissue Diseases

Date Applied
07/10/2022
Last Edited
10/10/2022
Date Assigned

Prospective/Retrospective

Overall Trial Status
Completed

Recruitment status
No longer recruiting

Study Information

Study hypothesis
Licochalcone A, Glycyrrhetinic acid and L-Carnitine containing sunscreen is effective is reducing acne and post acne hyperpigmentation.

Ethics approval
Approved 06/10/2021, Universiti Putra Malaysia Ethic Committee for Research Involving Human Subject (JKEUPM; +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

Trial setting
Hospitals

Trial type
Treatment

Overall trial start date
06/10/2021

Overall trial end date
30/07/2022

Overall trial status override

Reason abandoned (if study stopped)

Condition
Improve the treatment of acne and acne pigmentation

Interventions
Licochalcone A , Glycyrrhetinic acid and L-Carnitine containing sun block

Intervention Type
Other

Phase

Drug name(s)

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 …
5. Skin pH using …
6. Treatment related complications using …
7. Weight of cleanser, tretinoin and sunblock – determine compliance using ...
8. Patient satisfaction to treatment using …
9. Acne related quality of life using CADI

Trial website

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

Eligibility

Participant 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
Patient

Age group
Adult

Gender
Both

Target number of participants
56

Total final Enrolment
50

Participant 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.

Recruitment start date
01/03/2022

Recruitment end date
30/06/2022

Recruitment status override

Locations

Countries of recruitment
Malaysia

Trial participating centres

Trial Centre

Trial Centre Name
Universiti Putra Malaysia Teaching Hospital

Address
Persiaran Mardi - Upm

City
Serdang

Country
Malaysia

Zip
43400

Plain English Summary

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

Results and Publications

Publication and dissemination plan
Planned publication in a Q3 ISI indexed journal "Cosmetic"

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

Intention to publish date
30/10/2022

Participant level data
Data sharing statement to be made available at a later date

Basic results (scientific)

Results (plain English)

Publication list

Publication citation(s)

Contact(s)

Contact

Type
Principal Investigator

Title
Dr

Name
Kang Nien How

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

Address
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia

City
Serdang

Country
Malaysia

Zip
43400

Tel

03 9769 5601

Email
hkangnien@upm.edu.my

Privacy
Public

Sponsor(s)

Sponsor

Organisation
Beiersdorf (Malaysia)

Address
Level 12, Tower 1
PJ33, 3, Jalan Professor Khoo Kay Kim
Seksyen 13

City
Petaling Jaya

Country
Malaysia

Zip
46200

Tel
+60 3-7940 9668

Email
Wilson.Chew@Beiersdorf.com

Type
Industry

Website

Privacy
Public

Funder(s)

Funding Type
Industry

Funder

Funder Name
Beiersdorf

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Applicant Details

Name
Kang Nien How

ORCID ID

Address

City

Country

Zip

Tel

Email
hkangnien@upm.edu.my

Payment Method

Payment method
Online payment

Trusted funder

Invoice Details

Name

Institution

Address

City

State

Country

Zip

Email

Purchase order/ reference number

VAT number

Why did you choose ISRCTN to register your trial?
Previously registered a trial