ISRCTN45468017 https://doi.org/10.1186/ISRCTN45468017

Evaluation of atopic dermatitis using a topical moisturiser containing tocotrienol

Submission date
29/08/2022

Recruitment status
No longer recruiting

Registration date
05/09/2022

Overall study status
Completed

Last Edited
09/05/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Atopic dermatitis causes the skin to become itchy, dry and cracked. Little is known about the antioxidant effects of topical vitamin E on atopic dermatitis due to a lack of controlled clinical studies. Therefore this study aims to assess the effectiveness and safety of a moisturiser containing a tocotrienol-rich composition (REMDII Sensitive, Malaysia) on children with mild-to-moderate atopic dermatitis.

Who can participate?
Patients aged 1 month to 12 years with a diagnosis of atopic dermatitis

What does the study involve?
Each participant will be examined for signs and symptoms of atopic dermatitis before and after using REMDII Sensitive. Participants are instructed to exclusively use the moisturiser (REMDII® Sensitive Intensive Moisturising Cream) and body wash (REMDII® Sensitive Calming Body Wash) given and abstain from using other soap-based products and commercial moisturiser during the whole study period. In accordance with this, participants are advised to apply the study product (Remdii Sensitive) thrice daily on the affected atopic dermatitis lesion sites for 12 consecutive weeks. To ensure their compliance, each participant is requested to return the bottles at every visit to assess the amount of applied moisturiser. Mild potency corticosteroids such as hydrocortisone 1% cream are used for the first 2 weeks concurrently with the study product. Thereafter, the use is only limited to flare up. The utilization of corticosteroids is recorded in the provided diary.

What are the possible benefits and risks of participating?
There are no adverse effects known to be caused by REMDII Sensitive. REMDII Sensitive has been registered to the National Pharmaceutical Regulatory Agency (NPRA), Kementerian Kesihatan Malaysia with the notification number NOT181000506K and certified halal. All topicals can cause irritation, burning, stinging sensation and folliculitis. There is a low risk of sensitization to the topical ingredients. The study procedures are all routine procedures for the disease /condition studied. There is thus a minimal risk for subjects. All parties will be insured by trial insurance paid for by the sponsor.

Where is the study run from?
Lipidware Sdn Bhd (Malaysia)

When is the study starting and how long is it expected to run for?
February 2019 to February 2020

Who is funding the study?
Lipidware Sdn Bhd (Malaysia)

Who is the main contact?
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2. Prof. Lai Oi Ming, omlai@upm.edu.my

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
JKEUPM-2019-274 (NMMR-19-1588-49234)

Study information

Scientific Title
A Phase II open-label, single arm, single centre clinical study on the effect of a moisturiser containing tocotrienol-rich composition on mild to moderate atopic dermatitis in children

Acronym
Atopic Dermatitis

Study objectives
REMDII Sensitive significantly improves the severity of atopic dermatitis in children with mild to moderate atopic dermatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/08/2019, Universiti Putra Malaysia Ethic Committee for Research Involving Human Subjects (JKEUPM; Universiti Putra Malaysia, 43400 UPM Serdang, Selangor, Malaysia; +60 (0)3 97691605; jkeupm@upm.edu.my), ref: JKEUPM/1.4.18.2 (JKEUPM)

Primary study design
Interventional

Study design
Phase II open-label single-arm single-centre clinical study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Atopic dermatitis

Interventions
Each participant will be examined for signs and symptoms of atopic dermatitis before and after using REMDII Sensitive. Participants are instructed to exclusively use the moisturiser (REMDII® Sensitive Intensive Moisturising Cream) and body wash (REMDII® Sensitive Calming Body Wash) given and abstain from using other soap-based products and commercial moisturiser during the whole study period. In accordance with this, participants are advised to apply the study product (Remdii Sensitive) thrice daily on the affected atopic dermatitis lesion sites for 12 consecutive weeks. To ensure their compliance, each participant is requested to return the bottles at every

visit to assess the amount of applied moisturiser. Mild potency corticosteroids such as hydrocortisone 1% cream are used for the first 2 weeks concurrently with the study product. Thereafter, the use is only limited to flare up. The utilization of corticosteroids is recorded in the provided diary.

Intervention Type
Other

Primary outcome(s)
Atopic dermatitis severity measured using Investigator's Global Assessment (IGA) score at baseline, Week 0, Week 2, Week, 4, Week 8 and Week 12

Key secondary outcome(s)
1. Atopic dermatitis severity measured using Scoring Atopic Dermatitis Index (SCORAD) at baseline, Week 0, Week 2, Week, 4, Week 8 and Week 12
2. Atopic dermatitis severity measured using Infant Dermatology Life Quality Index (IDQOL) and Children's Dermatology Life Quality Index (CDLQI) at baseline, Week 0, Week 2, Week, 4, Week 8 and Week 12
3. Atopic dermatitis severity measured using Pruritis Score using Visual Analogue Score (VAS) or ordinal at baseline, Week 0, Week 2, Week, 4, Week 8 and Week 12
4. Frequency of rescue treatment needed, measured using the number of times hydrocortisone is required at baseline, weeks 0, 2, 4, 8 and 12
5. Atopic dermatitis severity measured using high-resolution ultrasound skin imaging (HR-USI), skin colour and transepidermal water loss (TEWL) at baseline, Week 0, Week 2, Week, 4, Week 8 and Week 12
6. Correlation between atopic dermatitis severity measured using SCORAD index and Patient-Oriented SCORing Atopic Dermatitis (PO-SCORAD) or IDLQI at each baseline and follow-up visit at weeks 0, 2, 4, 8 and 12 and absolute changes from baseline

Completion date
04/02/2020

Eligibility

Key inclusion criteria
1. Male and female ages 1 month to 12 years with a diagnosis of atopic dermatitis based on UK Working Party Criteria of Atopic Dermatitis (Williams, Jburney, Pembroke, Hay, & Party, 1994)
2. Individuals with an IGA score of at least mild (IGA= 2) or moderate (IGA= 3) and have at least 5% of body surface area affected during the inclusion time
3. Individuals with a carer reported pruritus score based on VAS of at least 40 mm and above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 Months

Upper age limit
12 Years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Patients with exacerbation which is not controlled by per protocol rescue medicine in 2 weeks.
2. Infection failed to be treated with per protocol oral antibiotic. Or those who develop cutaneous sepsis, as defined by skin infection + >/= 2 meets the SIRS definition, as defined below:
3. Temp >38.5°C or >36°C
4. Tachycardia or bradycardia (if <1 year)
5. Tachypnea or requiring mechanical ventilation
6. Abnormal leukocyte count or >10% bands
7. Infections which are not deemed related to atopic eczema i.e. pneumonia, UTI, AGE, will not be withdrawn even if fulfilled sepsis criteria.
8. The development of any severe adverse event, as defined by the Malaysian GCP
9. Use of any forbidden medication or treatment, and/or other use moisturisers or emollients during the trial that could affect the study result
10. Subjects who did not comply with the protocol of at least two times-per-day application of cream
11. Subject's withdrawal of consent
12. Detection of eligibility violations, occurrence of other significant protocol violations during the trial
13. Investigator's decision to terminate the process for the sake of the subject's health
14. Dropouts are defined as patients who did not attend a follow-up visit within the designated visit window (+/- 3 days) and whose outcomes are unknown by the end of the trial

Date of first enrolment
01/07/2019

Date of final enrolment
30/08/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
Hospital Pengajar Universiti Putra Malaysia
Persiaran Mardi - Upm
Serdang

Malaysia
43400

Sponsor information

Organisation
Lipidware Sdn Bhd

Funder(s)

Funder type
Industry

Funder Name
Lipidware Sdn Bhd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to anonymity arrangements made with the patients that data of personal nature will be made anonymous as much as possible.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/05/2023	09/05/2023	Yes	No
Participant information sheet			01/09/2022	No	Yes
Protocol file			01/09/2022	No	No