DEC033 Study Product for Mild to Moderate Eczema An Open-label, Adaptive-design Pilot Study

ClinicalTrials.gov Identifier: NCT02379507

Recruitment Status : Completed
First Posted : March 5, 2015
Last Update Posted : March 5, 2015

Sponsor:
Medicus Research, LLC

Information provided by (Responsible Party):
Medicus Research, LLC

Study Description

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Brief Summary:
This open-label, adaptive design study was designed to determine the efficacy of the study product in the treatment of eczema which would be assessed by the reduction of the appearance of skin lesions and symptoms associated such as itching, scaling and redness.

Condition or disease	Intervention/treatment	Phase
Eczema	Other: DEC033 Study Product	Phase 1

Detailed Description:

Eczema is an inflammatory skin disease characterized by itchy red rashes commonly found in the elbows or behind the knees. Eczema lesions may appear as collection of fluid in the skin (vesicles) or as gross thickening of the skin (lichenification) with redness. It is also associated with crusting, scaling, cracking, and swelling of the skin. Usually, it does not need medical treatment. However, a more severe form of eczema is referred to as atopic eczema or atopic dermatitis which occurs in childhood or early adulthood. The overall prevalence of this condition in Northern Europe is 15-20% of children aged 7-18 years. Atopic eczema greatly affects the quality of life of the individuals and in fact accounts for the highest scores when compared with other dermatological diseases. A child with eczema experiences itch and sleep disturbances, ostracism by other children, the need for special clothing and bedding, avoidance of physical activities such as swimming and the need for frequent application of ointments.

Eczema is commonly treated with antihistamine pills and creams or ointments. Antihistamines and steroid creams control the itching and rash caused by severe eczema. It is also recommended that the skin be well lubricated to prevent it from becoming dry. A systematic review of randomized clinical trials on atopic eczema summarized the interventions for treating the condition which include pharmacological drug type (topical steroids), similar intervention type (dietary measures) or convenience (non-pharmacological treatments).

Shea butter, which contains stearic acid, linoleic acid, and catechins (antioxidants), is processed from nut of the Vitellaria paradoxa tree. It is traditionally used as lotion for the skin and hair as it is considered an emollient and skin conditioning agent. It has also been of importance in soothing arthritic pains, reducing swelling, treating skin problems, and as antiseptic for wounds. Shea butter is also found in topical formulations used for inflammatory dermatoses such as psoriasis and atopic dermatitis. Shea butter consists of triterpene cinnamates and acetates and these were found to have anti-inflammatory activity which can help in the reduction of edema associated with eczema. Human clinical studies have demonstrated shea butter as skin aging treatment which regenerates skin and gives smoother, clearer skin. Wrinkles from photoaging were also diminished. Another trial showed that shea butter has cicatrizing action in 70% of cases of hand dermatitis, sun burns and scars. A cream with shea butter was also demonstrated to promote good moisturization of the skin compared to placebo.

Macadamia nut oil is one of the most heart-friendly oils. It contains vitamin E, omega-3, omega-6, oleic, linoleic, and palmitoleic acids. Macadamia oil decreases low density lipoprotein levels and increases high density lipoprotein levels thus reducing risk of heart diseases. There are various benefits of macadamia oil on skin. It provides moisturization and anti-aging effects. Palmitoleic acid, which is commonly found in the skin, decreases as people age. Macadamia oil helps replace the lost compound to maintain youthful skin. Blemishes and scars are also removed with the help of macadamia oil. It has anti-inflammatory activity and antioxidant effects thus reducing free radicals on the skin and providing healing of skin conditions such as sunburns.

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Study Design

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Study Type :
Interventional (Clinical Trial)

Actual Enrollment :
20 participants

Allocation:
N/A

Intervention Model:
Single Group Assignment

Masking:
None (Open Label)

Primary Purpose:
Supportive Care

Official Title:
DEC033 Study Product for Mild to Moderate Eczema An Open-label, Adaptive-design Pilot Study

Study Start Date :
January 2014

Actual Primary Completion Date :
June 2014

Actual Study Completion Date :
June 2014

Resource links provided by the National Library of Medicine

Genetics Home Reference related topics: Atopic dermatitis

MedlinePlus related topics: Eczema

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: DEC033 Study Product Apply twice a day	Other: DEC033 Study Product Apply twice daily

Outcome Measures

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Primary Outcome Measures :

1. Symptoms of Itching, Scaling, and Redness measured by Visual Analog Scale (VAS) [Time Frame: 30 days]

   Subjects completed the Visual Analog Scale for eczema symptoms - itching, scaling, and redness.

Secondary Outcome Measures :

1. Size and Severity of Eczema Lesions measured by Dermatologic Assessments [Time Frame: 30 days]

   Dermatologic assessments for severity and size of lesions and Severity Scoring of Atopic Dermatitis (SCORAD) were assessed by a practitioner in the clinic.

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years to 70 Years (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

Yes

Criteria

Inclusion Criteria:

- Healthy male or female ≥ 18 and ≤ 70 years of age.
- Body mass index (BMI) ≥ 20 and ≤ 35 kg/m2.
- Subjects with mild to moderate eczema; determined at screening visit.
- Judged by the Investigator to be in general good health on the basis of medical history.
- Agree to use the Study-supplied cleanser and moisturizer as the only body cosmetic applied to irritated skin.
- Agree to stop all medications and supplements during the entire length of the study
- Females of child bearing potential must agree to use appropriate birth control methods during the entire study period.
- Agree not to initiate any new exercise or diet programs during the entire study period.
- Agree not to change their current diet or exercise program during the entire study period.
- Understands the study procedures and signs forms providing informed consent to participate in the study and authorization for release of relevant protected health information to the study investigator.

Exclusion Criteria:

- Clinically significant renal, hepatic, endocrine (including diabetes mellitus), cardiac, pulmonary, pancreatic, neurologic, hematologic, or biliary disorder.
- Known allergy or sensitivity to Herbal products.
- History or presence of cancer in the prior two years, including any skin cancer or suspicious lesions.
- Recent history of alcoholism (within 12 months) or strong potential for alcohol or substance abuse.
- Participation in a clinical study with exposure to any non-registered drug product within 30 days prior.
- Individual has a condition the Investigator believes would interfere with his or her ability to provide informed consent, comply with the study protocol, which might confound the interpretation of the study results or put the person at undue risk. Including subjects who are Bed or wheelchair-bound.
- Pregnant, lactating, or unwilling to use adequate contraception during the duration of the study.
- Smoking - must be nonsmoker for at least 12 weeks prior to screening.

Contacts and Locations

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No Contacts or Locations Provided

More Information

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Responsible Party:

Medicus Research, LLC

ClinicalTrials.gov Identifier:

NCT02379507 History of Changes

Other Study ID Numbers:

DECI1200

First Posted:

March 5, 2015 Key Record Dates

Last Update Posted:

March 5, 2015

Last Verified:

January 2015

Keywords provided by Medicus Research, LLC:

mild to moderate

Additional relevant MeSH terms:

Eczema

Dermatitis

Skin Diseases

Skin Diseases, Eczematous