The Role of Skin Care Regimen in Skin Health

NCT03497130

April 5, 2018

Date: 04/05/2018

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Application Number: IRB00165140

JHM IRB - eForm A – Protocol

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1. Abstract

Dry skin is not a disease entity but it is an important patient matter as it can significantly decrease a person's quality of life. Individuals with dry skin experience discomfort associated with itching, skin tightness, and irritation. The lack of proper hydration is one of the most apparent characteristics of dry skin, which is associated with erythema and scaling on the skin surface. Skin care products with moisturizing features have beneficial effects in the treatment of dry skin. The aim of our study is to evaluate the role of a regular skin care regimen comprising of a mild cleanser and moisturizer in improving dry skin and overall skin health.

This study will have a study population of up to 100 individuals over the age of 18. Each study participant will have up to 3 on-site visits within 4 weeks. Select participants will be asked to apply a mild cleanser and moisturizer daily for 2 weeks. To assess the effects of a regular skin care regimen, clinical evaluations, digital photography, and subject questionnaires will be obtained during the study.

2. Objectives

- The primary aim of the study is to evaluate the role of a regular skin care regimen comprising of a mild cleanser and moisturizer in improving dry skin and overall skin health.
- The secondary aim of the study is to assess quality of life improvement with a routine skin care regimen.

3. Background

Dry skin is a common phenomenon and can dramatically decrease a person's quality of life as well as contribute to a wide variety of skin diseases. Individuals with dry skin experience discomfort associated with itching, skin tightness, and irritation[1]. The lack of proper hydration is one of the most apparent characteristics of dry skin, which is associated with erythema and scaling.[2] Dry skin is caused by the interaction of lifestyle and environmental factors. Hereditary factors and advanced age can also contribute to dry skin. The severity of dry skin is usually exacerbated by the frequent use of harsh cleansers, the lack of moisturization, and by cold, dry air[3,4].

Skin care products are topical preparations with mainly moisturizing feature which have beneficial effects on dry skin. Skin care products hydrate the skin and breaks the dry skin cycle[5]. There are many mild cleansers and moisturizers widely available for improvement of dry skin. However, many healthcare providers and patients overlook the importance of skin care products and a regular skin care regimen. Numerous studies show that usage of mild cleansers and moisturizers hydrates and improves dry skin and appearance.[6-13]. While there is extensive evidence of benefits of using mild cleansers and moisturizers, much of the previous studies are limited to the effects of

single cleanser or moisturizer. Skin care regimens incorporating regular use of a mild cleanser and moisturizer have not been assessed.[14-16]. This study aims to evaluate the role of a regular skin care regimen comprising of a mild cleanser and moisturizer in improving dry skin, skin appearance, and overall skin health.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures

Recruitment: Individuals will be recruited from patient populations seen at the general dermatology clinics of Johns Hopkins Department of Dermatology or from patient populations participating in Johns Hopkins Cutaneous Translational Research Program (CTReP) research studies. Interested study participants will be evaluated after their routine clinical care visits. Participants will also be recruited from other patient populations at the Johns Hopkins Hospital through the use of flyers and online advertisements. Study procedures will be conducted at the Johns Hopkins CTReP office located at the Johns Hopkins Outpatient Center. Recruitment may include Johns Hopkins University employees or students, but these groups will not be specifically targeted for participation. Interested individuals will be interviewed to ascertain whether they meet the basic eligibility criteria to participate in the study. Once eligibility has been demonstrated, the potential subjects will be directed to make their first study appointment. We will recruit up to 100 participants over the age of 18 with dry, itchy skin and they will be split into 2 groups. Participants will be randomly assigned to skin care regimen group (approximately 75% of total enrolled) and control group (approximately 25% of total enrolled). All evaluation will be conducted similarly in both groups.

Visit 1

During the first scheduled appointment, the research protocol will be discussed with the subject, and documentation will be obtained of the subject's consent to participate in the study as well as the subject's agreement to be contacted about future research studies.

Once informed consent is obtained, individuals will undergo a washout period of one week in which they are asked to refrain from the use of all moisturizers on their skin. Participants will be supplied with a skin cleanser, Dove® Soap, to use during this period and application log. All applications should be reported in the application log by the participants.

During this visit, investigators will also perform clinical assessment, take photographs and administer subject questionnaires.

Visit 2 (Baseline):

All participants will return after the washout period. Participants in the skin care regimen group will receive Vaseline® Moisturizer, Dove® Soap, and application log. These participants will be asked to apply the Vaseline® Moisturizer twice a day and use Dove® Soap daily for 2 weeks. All applications should be reported in the application log by the participants. A demonstration and verbal instructions for how and where to apply the products will be provided to the subjects along with the application log for daily use. Individuals not in the skin care regimen group will continue with the provided Dove® Soap.

During this visit, investigators will perform clinical assessments, take photographs and administer subject questionnaires.

Visit 3 (day 14±2):

During this visit, investigators will perform clinical assessment, take photographs and administer subject questionnaires. Application logs will be returned.

Clinical assessment: Clinical assessments will be performed 1) to record baseline skin findings, 2) to evaluate skin status by visual scoring, and 3) to identify any occurrence of any adverse events.

Photography: Standardized digital photographs will be obtained by study staff using a digital camera and software under standard photographic conditions. Photograph files will be coded to remove personal identifiers and stored on a secure hard drive in CTReP.

b. Study duration and number of study visits required of research participants.
The study consists of up to 3 on-site visits within 4 weeks. We will allow 1 year to complete the study.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.
NOT APPLICABLE

d. Justification of why participants will not receive routine care or will have current therapy stopped.
NOT APPLICABLE

e. Justification for inclusion of a placebo or non-treatment group.
NOT APPLICABLE

f. Definition of treatment failure or participant removal criteria.

Any clinical findings determined by the Investigator to be important and/or unusual will be referred to as an adverse event (AE). Study participants will be asked to contact clinic staff immediately if they experience an adverse reaction to the products at any time during the study.

Such reactions may be documented in a problem events log. The Investigator will use her discretion to remove participants from the study, and all problem events will be reported to IRB.

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
NOT APPLICABLE

5. Inclusion/Exclusion Criteria

Inclusion:

1. Participants must be over the age of 18 years old with dry, itchy skin;
2. Participant must be willing to comply with the requirements of the protocol;
3. Participant must have the ability to understand and communicate with the investigator;
4. Participant must provide informed consent.

Exclusion:

1. Subjects who are unable to provide informed consent;
2. Subjects who are unable to refrain from swimming or hot tub use or no more than 2 showers per day throughout the study duration
3. Subject with significant medical history or current skin diseases that the investigator feels is not safe for study participation;
4. Subjects who have been treated with systemic retinoids or steroids within the past month prior to entry to the study;
5. Subjects who have been treated with topical steroids, retinoids or other topical drugs within 2 weeks prior to entry to the study;
6. Recently treated or current skin diseases that would affect clinical evaluation;
7. Subjects who self-report that they are pregnant or nursing;
8. Patients with history of investigational drug use in the 30 days prior to entry into the study.

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used.

NOT APPLICABLE

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.

NOT APPLICABLE

c. Justification and safety information if non-FDA approved drugs without an IND will be administered

NOT APPLICABLE

7. Study Statistics

a. Primary outcome variable.
Clinical/visual scores and subjective score from subject questionnaires.

b. Secondary outcome variables.
Adverse effects reported by participants and investigator.

c. Statistical plan including sample size justification and interim data analysis.
Analysis will include paired and unpaired t-tests with two-tailed p-values. Values obtained at baseline, in middle of the study and after completing the study will be compared. The difference of measure values will be compared between application group and control group.

d. Early stopping rules.
If the participant wishes to withdraw from the study for any reason, or if the primary caretaker or study investigators wish to cease use of the products.

8. Risks

The moisturizing lotion and wash are generally very well tolerated. Rarely, they can induce a burning sensation, dryness, skin irritation, erythema, stinging, sensitization, and dermatitis. Possible side effects from the product applications include irritant and allergic reactions. Irritation from these agents can be improved or relieved when participants stop using the products. Risk events, problems, and deviations will be reported by the PI directly to the IRB.

In terms of confidentiality, there are minimal risks as all study participant information will be de-identified. No confidential or protected information would be taken beyond the standard. There is a slight financial risk to the participants in the rare event that the above complications occur, requiring additional medical care.

9. Benefits

Patients with dry skin in the skin care regimen group may experience improvement in their overall skin health. There will be no direct benefit to the participants in the control group. In addition, there is also the potential benefit to society at large. We hope to assess the role of a routine skin care regimen in improving dry skin and reducing symptoms. This can improve quality of life for patients who suffer from dry skin.

10. Payment and Remuneration

Study participants who undergo all study procedures, including correct application of moisturizing lotion and wash in the skin care regimen group will receive a total of $60 at completion of the study.

11. Costs

Study costs will be covered by the UniLever Corp.

12. References

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