A Single Center, Clinical Study to Determine the Safety and Efficacy of an Avena Sativa Skincare Regimen for Therapy-Related Pruritus and Xerosis in Cancer Patients

Prepared for:

Johnson & Johnson Consumer Inc.

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PURPOSE

Skin reactions due to cancer treatments are common. Many patients undergoing cancer therapies experience various types of skin reactions including dry skin, rash, itchiness, hyperpigmentation, flushing, etc. Among the most common skin reactions associated with chemotherapy, immunotherapies, allogeneic hematopoietic stem cell transplantation (alloHSCT), or targeted therapies are dry skin and itch (Skin Conditions, 2012).

To address the symptoms of dry skin, doctors normally recommend patients to moisturize his/her skin frequently and regularly. Moisturizers are an important part of a cancer patient's skincare routine because moisturizers create a barrier on the skin that helps prevent water loss. Symptoms of localized itch are normally addressed with topical over-the-counter (OTC) anti-itch products containing menthol, camphor, or pramoxine or topical and oral antihistamines or corticosteroids.

Because of the delicate nature of the skin of patients undergoing cancer treatment therapy(ies), skincare products should be gentle, mild, and free of perfumes, harsh soaps, and lanolin. Skincare products containing Avena sativa kernel oat flour have a long history of tolerance and efficacy in various therapeutic skin conditions involving pruritus and xerosis including eczema, psoriasis, diabetic skin, rashes, contact dermatitis, etc. (Kurtz et al, 2007, Criquet et al, 2012). Avena sativa kernel oat flour is an ingredient known for its skin protectant properties and its soothing effects on the skin (Fowler, 2014). Avena sativa kernel oat flour contains a number of components including starches, polysaccharides, proteins, lipids, antioxidants, and phenolic acids (avenanthramides). Starches contribute to the creation of an occlusive film (protectant) on the skin (IInytska et al, 2016) and to the oats' humectant (water binding) activity. Lipids are important for the skin barrier. Avenanthramides are phenolic compounds of oat which have been shown to have anti-inflammatory properties in in vitro studies (Sur et al, 2008).

This single-center, open-label clinical trial was conducted for Johnson & Johnson Consumer Inc. to determine the safety and efficacy of a fragrance-free skincare regimen consisting of an Avena sativa oat kernel flour body wash, body cream, and anti-itch balm with 0.5% pramoxine on patients undergoing various cancer treatments who were experiencing mild to moderate pruritus and/or xerosis.

GENERAL INFORMATION

Johnson & Johnson Consumer Inc. Study Number:	CCSSKA000844
Test:	A Single Center, Clinical Study to Determine the Safety and Efficacy of an Avena Sativa Skincare Regimen for Therapy-Related Pruritus and Xerosis in Cancer Patients
Investigational Study Materials:	Body Wash Body Cream Anti-itch Balm
Principal Investigator (PI):	Mario E. Lacouture, M.D. Memorial Sloan-Kettering Cancer Center New York, NY 10022
Study Site:	Memorial Sloan-Kettering Cancer Center New York, NY 10022
Sponsor:	Johnson & Johnson Consumer Inc. 199 Grandview Road Skillman, NJ 08558
Testing Start Date:	23 May 2019
Testing End Date:	18 Dec 2019

SUMMARY

This single-center, open-label clinical trial was conducted for Johnson & Johnson Consumer Inc. to determine the safety and efficacy of a fragrance-free skincare regimen consisting of an Avena sativa oat kernel flour body wash, body cream, and anti-itch balm with 0.5% pramoxine on patients undergoing various cancer treatments who were experiencing mild to moderate pruritus and/or xerosis.

The target population was 18- to 75-year-old male and female subjects who had a prior diagnosis of a solid or hematologic tumor. Subjects had to be undergoing therapy with a systemic agent (completed ≥ 3 cycles), received therapy with a systemic agent within 28 days of screening, or had to be status post alloHSCT (> 1-year timeframe). Additionally, subjects had to be diagnosed with either grade 1 or 2 Common Terminology Criteria for Adverse Events (CTCAE) skin events for xerosis (<10% body surface area [BSA] or 10-30% BSA) or pruritus (mild/localized or widespread and intermittent).

A total of 52 subjects were enrolled into the study and 40 subjects completed study participation. Of the 52 enrolled subjects, 46 of them were included in the Full Analysis Set (FAS), defined as all subjects who used the Investigational Products (IPs) and had Baseline and at least one post-baseline data point; and 48 of them were included in the Adverse Event (AE) analysis set, defined as all subjects who used the IP.

During the course of the study, subjects were provided with the Investigational Body Wash (to use daily), Body Cream (to use twice daily), and Anti-Itch Balm (localized use as needed, no more than three to four times daily) to be used for the duration of the study.

Subjects were evaluated by the PI at Visit 1 (Screening/Baseline) and Visit 2 (Week 5/Final Visit, ±1 week). Subjects participated in the following procedures at the indicated time points:

- Common Terminology Criteria for Adverse Events (CTCAE) for Xerosis and Pruritus
  At Screening/Baseline and Week 5/Final Visit, the PI or Sub-Investigator (Sub-I) assessed each subject's skin for overall xerosis (dry skin) and pruritus (itch) using the CTCAE version 5.0 grading (severity) scale.

  To qualify for study participation, each candidate subject must have exhibited Grade 1 or Grade 2 CTCAE symptoms for xerosis (dry skin) (<10% BSA for Grade 1 or 10-30% BSA for Grade 2) and/or pruritus (itch) (mild/localized or widespread and intermittent) at the time of study enrollment.

- Eastern Cooperative Oncology Group (ECOG) Performance Status
  At Screening/Baseline, the PI or Sub-I assessed each subject for ECOG performance status.

  To qualify for study participation, each candidate subject must have had ECOG performance status of 0-2 at the time of study enrollment.

- Global Overall Evaluations
  At Screening/Baseline and Week 5/Final Visit, the PI or Sub-I assessed each subject's skin for global overall xerosis (dry skin) and overall irritation; and questioned each subject for global overall pruritus (itch) and recorded the subject's response.

- Overall Tolerance Assessment
  At Week 5/Final Visit, the PI or Sub-I assessed how well each subject tolerated the study regimen and questioned each subject on how well the subject felt he/she tolerated the study regimen and recorded the subject's response.

- Corneometer Measurements
  At Screening/Baseline and Week 5/Final Visit, three measurements were taken from each subject's left volar forearm using a Corneometer CM 825 (Courage + Khazaka, Germany) to measure the moisture content in the stratum corneum by an electrical capacitance method.

- Transepidermal Water Loss (TEWL) Measurements
  At Screening/Baseline and Week 5/Final Visit, three measurements were taken from each subject's right volar forearm using a Delfin VapoMeter (Delfin Technologies Ltd., Kupio Finland) to measure the transepidermal water loss (TEWL).

- Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)
  At the study site (Screening/Baseline and Week 5/Final Visit), each subject completed the PRO-CTCAE questionnaire for skin dryness and itching.

- Skindex-16 Questionnaire
  At the study site (Screening/Baseline and Week 5/Final Visit), each subject completed a Skindex-16 questionnaire, a self-reported dermatology-specific quality of life (QOL) questionnaire.

- Skin Attributes Self-Assessment Questionnaire
  At the study site (Screening/Baseline and Week 5/Final Visit), each subject completed a Skin Attributes Self-Assessment questionnaire rating their overall skin condition.

Overall Conclusions

Overall results from this single-center, open-label clinical trial indicate that the Sponsor's fragrance-free skincare regimen [consisting of an Avena sativa oat kernel flour body wash, body cream, and anti-itch balm with 0.5% pramoxine] was effective in improving therapy-related pruritus and xerosis in patients undergoing various cancer treatments (as outlined in the study eligibility criteria) who were experiencing mild to moderate pruritus and/or xerosis, under the conditions of this test. The regimen was well tolerated as perceived by both the PI or designee and the subjects.

Results for the primary endpoints

Results of the Common Terminology Criteria for Adverse Events (CTCAE) evaluations showed a statistically significant ($p \leq 0.05$) improvement in xerosis (dry skin) and pruritus (itch) at Week 5/Final Visit when compared with Baseline.

Results of the clinical evaluations showed a statistically significant ($p \leq 0.05$) improvement in global overall xerosis (dry skin) (as evaluated by the PI or Sub-I) and global overall pruritus (itch) (as reported by the subjects) at Week 5/Final Visit when compared with Baseline.

Results of overall irritation showed a statistically significant improvement in overall irritation. However, overall irritation scores were minimal at Baseline and remained minimal (below slight) at Week 5/Final Visit.

Results for the secondary endpoints

Results of the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) questionnaire showed a statistically significant ($p \leq 0.05$) improvement in severity of dry skin and itchy skin at Week 5/Final Visit when compared with Baseline.

Results of the Skindex-16 questionnaires showed a statistically significant ($p \leq 0.05$) improvement in subject response values for each subscale [symptoms subscale (question items 1 – 4), emotional subscale (question items 5 – 11), functional subscale (question items 12 – 16)], and global score at Week 5/Final Visit when compared with Baseline.

Results of the Skin Attributes Self-Assessment questionnaire showed a statistically significant ($p \leq 0.05$) improvement in subject response values for all attributes (dryness, skin flakiness, itchiness of skin, skin roughness/texture, skin smoothness, softness, skin comfort, and overall look and feel of skin) at Week 5/Final Visit when compared with Baseline.

Results of the Corneometer measurements showed a statistically significant ($p \leq 0.05$) improvement in skin hydration at Week 5/Final Visit when compared with Baseline.

Results of the transepidermal water loss (TEWL) measurements showed a decrease (improvement) in values at Week 5/Final Visit when compared with Baseline; however, at $p = 0.099$, it was not statistically significant ($p > 0.05$) but showed a trend towards improvement.

After 5 weeks (±1 week) of use, the study regimen was deemed "well tolerated" by 95% of the subjects, "tolerated" by 2.5% of the subjects, and "not tolerated" by 2.5% of the subjects as assessed by both the PI or Sub-I and the subjects.

Adverse events

Study Related (study regimen):

2 subjects:
- Grade 1: Possible relationship (Mild rash)
- Grade 2: Possible relationship (Moderate erythema)*

Cancer Therapy Related:

1 subject:
- Grade 2: Possible relationship (Moderate erythema)*

Note: The same adverse event was classified as both possibly study-related and possibly cancer therapy related.

No deaths, other SAEs, or other significant adverse events were reported/observed in this study.

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REPORT APPROVAL

Report approved by:

Adegboyega Adenaike

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DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=1052812, cn=Adegboyega Adenaike
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Study Manager

Date