Randomized Double-Blind Study Assessing Safety and Efficacy of SQIN™ on Xerosis in Subjects with Mobility Impairment and Paralysis

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Abstract

In the general population, xerosis is often considered a reversible condition triggered by external factors such as seasonal changes. However, for individuals suffering chronically of mobility problems due to age, paralysis (e.g., spinal cord injury, multiple sclerosis, Parkinson's, etc.) or related metabolic problems (e.g., diabetes), xerosis generally severe and chronic because of permanently dysregulated systems (e.g., dermatologic, vascular, hormonal). Although standard, commercially available moisturizers can improve dry skin problems if mild and acute, they generally do not reverse severe and chronic xerosis. We performed a double-blind, randomized pivotal phase II/III study to assess the safety and efficacy of SQINTM with CanSATs technology that comprises a complex blend of medicinal organic ingredients. SQINTM was applied on one side of the body whereas the active comparator was applied on the other side twice a day during 14 days. Self-assessment by spinal cord injured subjects was performed using a 5 level scoring scale. The results showed a 61.9% decrease of dryness accompanied by a nearly two-fold increase of elasticity induced by SQINTM whereas pruritus level was reduced by 50%. Although some effects were found also with the active comparator, the relative effects induced by SQINTM were significantly greater than those found with the control as illustrated also by the global appreciation factor -89.9% of all responding subjects preferred SQINTM over the active comparator. This study provides clear evidence that a complex blend of medicinal ingredients known for complementary actions upon multiple dermatological mechanisms can elicit potent synergistic-like effects on extensive chronic dry skin problems.

INTRODUCTION

Spinal cord injury (SCI) generally leads to an immediate and irreversible loss of sensation and voluntary muscle contraction below injury level as well as to a rapid development of severe health problems such as osteoporosis, muscular atrophy, immune deficiency, hormonal dysregulation, vascular, infertility, autonomic dysreflexia, diabetes, obesity, cardiovascular complications, sexual dysfunction, bladder and bowel problems [1]. Most people with SCI suffer also of chronic dry skin problems clinically referred to as xerosis that is typically accompanied of scaling and itching, a condition called pruritus. Xerosis and pruritus are caused directly by natural moisture being drawn out from the skin. Normal moisture level is critical to protect skin integrity and the body against infections. If only found occasionally (e.g., due to seasonal changes), xerosis can be improved simply with commercially available moisturizers (e.g., Cetaphyl, Eucerin or Glaxal Base). However, for those suffering of metabolic problems such as diabetes and/or mobility problems due to age or paralysis (spinal cord injury, multiple sclerosis, Parkinson’s, Alzheimer’s, muscular dystrophy, amputation, cerebral palsy, or other comparable disorders), xerosis is known to poorly respond to standard moisturizers given the severity and profound dryness caused by multiple dysregulated factors affecting natural skin moisture (e.g., metabolic, hormonal and vascular problems directly affecting skin health and integrity) [2-4].

Given our established leading expertise in the discovery and development of pharmaceutical drug combination products for chronic SCI, multiple sclerosis, diabetes and comparable disorders [5-7], we launched in 2013 a research program aimed at identifying an innovative blend of medicinal ingredients derived from plants capable, when properly combined, to exert...
powerful synergistic-like effects against xerosis. That novel approach, called CanSATs – which stands for Co-Activation of Natural Synergistically Acting Target-receptors, has been pivotal in identifying the candidate product called SQIN™. As active ingredients, the latter is essentially composed of shea butter, urea, glycerin, almond oil, canola oil, black tea and tea of Labrador. This pivotal clinical trial aimed at determining clearly whether or not SQIN™ is more efficient than best-selling moisturizers. In brief, the results showed that spinal cord-injured subjects with severe xerosis, approved to participate to this study, considered SQIN™ a potent product capable of significantly reducing severe xerosis and pruritus.

MATERIALS AND METHODS

This is randomized, double-blind, and controlled (positive control) study with volunteers suffering of a SCI and experiencing chronically dry or extremely dry skin. All experimental procedures were approved by an independent ERB committee (Veritas IRB approved April 7th, 2015). The protocol was publically release on https://clinicaltrials.gov/ct2/show/NCT02429206. Ten (10) spinal cord-injured participants (i.e. completely or incompletely paralyzed) were enrolled for this study. Prospective subjects were both men and women of any ethnicity/race. The proposed research did not involve vulnerable populations such as children, pregnant or lactating women, or elderly above 75 years of age.

Inclusion criteria

- Paralyzed due to a spinal cord injury (traumatic or non-traumatic origin)
- Chronically injured (at least 3 months post-injury)
- Paraplegic or tetraplegic
- 18-75 years of age
- Men and women
- French-speaking

Exclusion criteria

- Acute or subacute stage (within 1 day and 3 months post-injury)
- Had tumor(s) (malignant or non-malignant) of the skin in the last five (5) years
- Allergic or hypersensitive to glycerin or urea
- With psychiatric or mental disorder(s)
- Children (younger than 18 year-old) or elderly (older than 75 years of age)
- Not French-speaking

Testing procedures

Each participant received two jars – both identical in color, size and shape (white round 50 g jars). One was identified as jar A with a sticker on its cover whereas the other was identified as jar B with a corresponding sticker on its cover. As determined by the randomization procedures, jar A contained either 30 g of SQIN™ or 30 g of Glaxal Base®. Jar B automatically contained the other cream either SQIN™ or Glaxal Base®. Each volunteer was asked to self-administered, on dry skin areas found bilaterally on his/her legs or arms, a small amount (approximately 1 ml – that is one quarter of a teaspoon) of cream ‘A’ on the left side, and corresponding amount of cream ‘B’ on the right side.

The volunteer was asked to rub the cream for 15 seconds on each side to ensure equal penetration. This was repeated every morning and every evening approximately at the same time for 14 consecutive days.

Experimental product and positive comparator

As active natural ingredients, SQIN™ is composed of a proprietary combination of organic butyrospermum parkii, USP grade carbamide, USP grade glycerin, organic almond oil, organic canola oil, organic black tea, organicedumgroenlandicum tea, organic white tea, and paraffinumliquidum. As inactive ingredients, it contains highly purified reverse osmosis water, cetearyl alcohol, cereareth-20, sodium phosphate, and p-chloro-m-cresol. The positive comparator is Glaxal Base® as sold in pharmacy. The latter was chosen over other moisturizing cream because it one of the most-extensively used products, even approved by dermatologists for use in children, and typically used by pharmacists for compounding products. In fact, in the Over the Counter Counselling and Recommendation Survey conducted by industry magazines Drugstore Canada and L’Actualité Pharmaceutique, Glaxal Base® was voted the number-one choice in the Moisturizer/Dry Skin category. Glaxal Base® Moisturizing Cream and Glaxal Base® Moisture Therapy Lotion are widely acknowledged as standard moisturizers for skin that’s undergone harsh treatments as well as everyday dry, itchy skin conditions. Glaxal Base® is one of the many quality over-the-counter products offered by the privately-held WellSpring Pharmaceutical Corporation.

Outcome measures

As primary endpoints, self-assessment (qualitatively using a 5-point scale) of changes in skin appearance and condition (less dry, smoother, elasticity change, general appreciation).

Scale’s levels:
- score 1 for low level;
- score 2 for medium level;
- score 3 for high level;
- score 4 for very high level;
- score 5 for extreme level.

As secondary endpoints, appearing signs of side effects/adverse events (redness, irritation).

Statistical analysis

Student t tests were used. P values < 0.05 were considered as statistically significant.

RESULTS

Figure (1) shows that the experimental product SQIN™ reduced skin dryness. Using a 5-level score system where 1 is...
low level and 5 is extreme level, an average dryness score of 3.22 was found prior to testing. That level was significantly ($P < 0.05$) reduced to only 1.55 (left end panel) after 14 days of testing (left end panel). Skin elasticity level was also improved after 14 days of testing since an average elasticity level score of 2.11 found prior to testing, significantly ($P < 0.05$) increased to 4.11 after testing (center panel). Finally, itchiness or pruritus level went from an average score of 2.5 down to 1.25 after 14 days of testing (right end panel).

Figure (2) also illustrates that some effects were induced by the positive comparator Glaxal Base® (GB – Ctr). Indeed, an average dryness score of 3.00 found prior to testing was significantly ($P < 0.05$) reduced to 1.87 after testing (left end panel) whereas skin elasticity level went from 2.00 before up ($P < 0.05$) to 3.62 after testing (center panel). Pruritus level significantly ($P < 0.05$) decreased from 2.5 down to 1.5 on a 5-level scale after 14 days of testing (right end panel).

Figure (3) illustrates the results compared between the two tested products. Relative improvement values compared with control are reported as percentages. SQINTM elicited more beneficial effects on dryness than the control. Indeed, dryness was improved ($P < 0.05$) by 61.9% on the side treated by SQINTM and to a lesser extent by GB which reached only 37.7% of improvement (left end panel). This constitutes a nearly two-fold increase in benefits on dryness induced by SQINTM compared with control. Elasticity was also further improved ($P < 0.05$) by SQINTM than by GB given improvement levels that reached 94.7% and 81.0%, respectively (center panel). However, regarding itchiness, non-significantly different levels ($P > 0.05$) of improvement was found since 50% and 40% were reported by SQINTM versus GB, respectively (right end panel).

Figure (4) illustrates that 89.9% of all responding subjects treated significantly ($P < 0.05$) preferred, overall, the effects and qualities of SQINTM over the control Glaxal Base®. This result provides clear evidence that the experimental product is superior to the control product. Finally, no side effect or adverse event was reported by any of the volunteers who participated to this study.
DISCUSSION

The results show that SQIN™ was significantly more potent than the active comparator and best-selling moisturizer Glaxal Base® against xerosis and pruritus during this 14-days study. Several reasons may explain this finding. Firstly, it is well-recognized by researchers in this field that most moisturizing creams currently available commercially exert only moderate and short-lasting effects against dry skin due to a relative lack of active ingredients [8,9]. In contrast, SQIN™ comprises several active ingredients and molecules shown to act upon various cellular mechanisms directly involved in restoring elasticity, protecting against damages caused by aging or UVA/UVB rays, and stimulating collagen production for repair. In fact, each natural element constituting SQIN™ is made of a distinctive set of key molecules that promotes skin health. For instance, butyrospermumparkiiis rich in natural oils and vitamins (A, D, E, K, etc.), carbamide is one of the best natural moisturizing factors (NMFs) and a significant source of nitrogen whereas black tea possesses the a flavins-2, alkylamins, vitamins and minerals (B2, C, E, magnesium, potassium, zinc, polyphenols, tanins, etc.) [10-20]. In brief, SQIN™ constituents, studied separately, have clearly been shown by scientists to increase skin elasticity, self-repair, tissue penetration (acting as carrier), water-absorption, and antibacterial or antioxidant activities while decreasing inflammation, melanoma development, wrinkle formation and other signs of aging [10-20]. Secondly, SQIN™ is probably one of the safest products on the market. Indeed, unlike SQIN™, most standard moisturizers are made of molecules that figure on David Suzuki’s list of banned cosmetic ingredients because of their significant potential toxic or carcinogenic effects –e.g., parabens, industrial colorants, allergenic agents, fragrances, phthalates, colorants including coal tar dyes, DEA-related ingredients, PEG compounds (polyethylene glycol), formaldehyde-releasing preservatives, and other preservatives such as BHA and BHT (http://davidsuzuki.org/issues/health/science/toxics/dirty-dozen-cosmetic-chemicals/). The creation of SQIN™ by our team of neuroscientists was enabled by a proprietary technological platform aimed at easing in vivo drug screening and, hence, accelerating the identification of innovative combination therapies for dysfunctions and diseases generally experienced by people with mobility impairment and related diseases [5, 7]. In fact, that platform had been previously used and validated in 2004 when discovering the first oral drug ever capable of restoring temporarily episodes of walking in animal models of paraplegia [6,21] as well as several other comparable therapies since then against bladder and bowel problems or sexual dysfunctions associated with paralysis (e.g.,[22]). Applied to the field of medicinal herbal products, that breakthrough approach became CanSATs that stands for Co-Activation of Natural Synergistically Acting Target-receptors [23]. In 2013, that CanSATs approach enabled the identification and early development of SQIN™ against severe and chronic xerosis and pruritus.

CONCLUSION

This study clearly shows that SQIN™ is a potent product capable of significantly reducing severe xerosis and pruritus in people suffering a traumatic or non-traumatic SCI. Given that...
SQIN™ is essentially composed of safe and organic plant-derived substances as active ingredients, it may constitute a suitable product for long-term use and sustained application typically in vulnerable populations afflicted by extensive skin problems due to chronic paralysis or comparable mobility impairment diseases. As typically conducted with products (e.g., pharmaceuticals) with active ingredients, post-market surveillance and phase IV data will be collected in the next couple of years to further confirm safety and efficacy over long-term use of this product.

REFERENCES


