A Controlled, Double-Blind and Randomized Study for Evaluation of the Efficacy and Safety of Invel® Actiive Shirt with Invel® Technology

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Introduction

Lumbar pain (or low back pain) reaches epidemiclevels in the world population. It is estimated that 70-85% of the population will have low back pain at some point in their lives.

Given the chronic and debilitating nature of low back pain, it is imperative to explore new procedures that offer minimal risk during usage while simultaneously enhancing the patients' quality of life. Long-wave infrared phototherapy has been evaluated in some clinical studies that showed decrease and alleviation of pain in patients with column pain. [1, 2] And the shirt, Invel® Actiive Shirt, can be used as a non-invasive and practical coadjuvant therapeutic tool that could be incorporated in orientations for those who suffer from pains along the vertebral column.

Objective

Primary objective: To assess the effectiveness of the Invel® Actiive Shirt in relieving low back pain, particularly muscle pain.

Secondary objective: To evaluate safety in the use of the product.

Methodology

This study is a national, single-center, randomized, double-blind, and placebo-controlled trial involving a sample of 70 subjects who have a history of chronic low back pain persisting for at least 3 months prior to their inclusion in the study.

Investigational product: Invel® Actiive Shirt.

Methodology

The subjects were randomized into two groups. One of the groups used the shirt Invel® Actiive Shirt (group A) and the other used shirt with no Invel® technology (group B). The subjects were treated for 14 days and evaluated at times 0, 7 and 14 days.

Means of evaluation:

(a) GI-1: Global impression of improvement of pain is evaluated;
(b) Product safety was evaluated based on the percentage of patients who did not experience any serious or non-serious adverse events attributed to the use of the product.
(c) Thermography: To assess superficial blood perfusion.

Results

A total of seventy (70) subjects, with an average age of 48.38 years, including 77.75% women, were included in the study. The subjects were randomly assigned, and the study concluded with 29 subjects using the Invel® Actiive Shirt and 25 subjects using a shirt without Invel® technology.

Improvement of Pain:

With respect to the global impression of improvement, in visit 3, there was statistically significant difference between the two (A and B) groups (p = 0.0362).

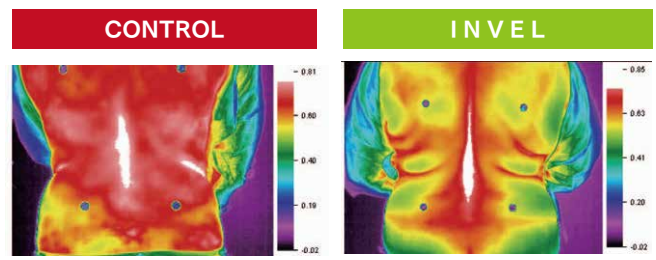
The obtained results were "improved a lot" (A: 24.14% vs. B: 4%) and "moderately improved" (A: 44.83% vs. B: 28%).

Thermography:

The white area in the image represents the stricken low back region and the red area represents the area of increase of blood perfusion. The decrease in size of the white area was compared between visits V1 and V3 in the two treatment groups A and B. We observed that improvement of the thermographic pattern of group A was 24% vs. 11% of the control group, group B.

Safety:

No clinically significant event was verified in the studied population.



Conclusion

The heat generated on the surface of the Invel® Actiive Shirt's fabric is a result of a photochemical effect. This effect leads to an increase in tissue perfusion, which aids in the removal of pain-causing substances and enhances oxygen supply to the affected area. It's important to note that the use of this product does not provide a cure for the underlying condition, but rather serves as an adjunctive resource in the treatment of low back pain. The heat generated by long-wave infrared radiation helps alleviate painful symptoms by preparing the affected region for the application of other conventional therapies.

ANVISA, National Health Surveillance Agency, recognized the efficacy and safety of this product and granted the registration ANVISA MS No. 80104760005 on 01/18/2011.

References

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Acknowledgments

This research was financed by INVEL,. (GOEN3 Industria e Comercio de Artigos para a Saude Ltda).
Research developed by IITP. (Instituto Invel de Tecnologia e Pesquisa).