

A CONTROLLED, DOUBLE BLIND AND RANDOMIZED STUDY FOR EVALUATION OF THE EFFICACY AND SAFETY OF INVEL® ACTIVE SHIRT WITH INVEL® TECHNOLOGY.

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Introduction

Lumbar pain (or low back pain), especially, reach epidemic levels in world population. It is estimated that 70 - 85% of the people will have low back pain in some time in life.

Since low back pain is chronic and often incapacitating, search for new procedures which present low risk of use and promote increase of the patients' quality of life is necessary. Long-wave infrared phototherapy has been evaluated in some clinical studies that showed decrease and disappearance of pain in patients with column pain. (1, 2) And the shirt, Invel® Active 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 evaluate the efficacy of the shirt, Invel® Active Shirt, in low back pain, especially muscle pain.

Secondary objective:

- To evaluate safety in the use of the product.

Methodology

A national single-center randomized, double blind, placebocontrolled study including a sample of 70 subjects with history of chronic low back pain with at least 3 months of progress on the date of inclusion.

Investigational product:

Invel® Active Shirt.

Methodology

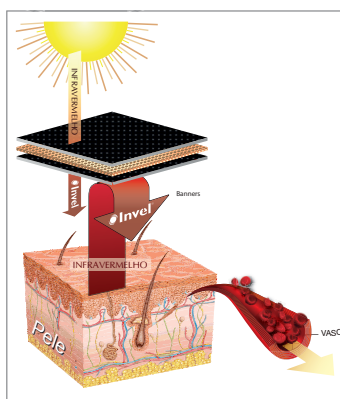
The subjects were randomized into two groups. One of the groups used the shirt Invel® Active Shirt (group A) and the other used shirt with no Invel® technology (group B). The subjects were treated for 14 days and evaluated at times 0, 7 and 14 days.

Means of evaluation:

- GI-1: Global impression of improvement of pain is evaluated;
- Product safety was measured by the proportion of patients that did not present serious or non-serious adverse events, related to the use of the product;
- Thermography: To assess superficial blood perfusion.



44% reduction in back pain



Mechanism of Action

Results

Seventy (70) subjects from both genders (77.75% women), average age 48.38 years old were included. The subjects were assigned at random, but the study was concluded with 29 subjects that used the shirt Invel® Active Shirt and 25 the shirt with no Invel® technology.

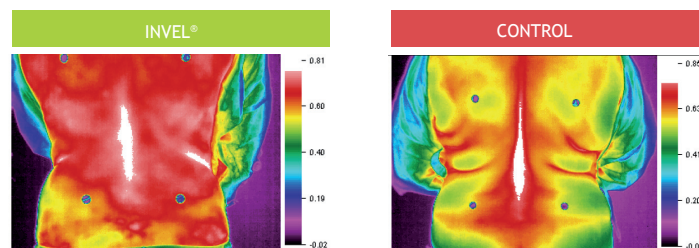
Improvement of Pain:

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 surface heat promoted by the Fabric of Invel® Active Shirt is result of a photochemical effect. It occurs due to increase of tissue perfusion promoted by heat, aid in the removal of substances that cause pain and increase of oxygen supply to the site. The use of the product does not lead to cure of the disease, but it is an auxiliary resource in the treatment of low back pain. The heat promoted by long-wave infrared radiation attenuates painful symptoms by preparing the stricken region for the application of other traditional 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.

Reference

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