



Double Blind, Placebo Controlled, Crossover Trial on the Effect of Optically Modified Polyethylene Terephthalate Fiber Mattress Covers on Sleep Disturbances in Patients with Chronic Back Pain

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Seth Casden, CEO
Hologenix, LLC
1112 Montana Ave., Suite 13
Santa Monica, CA 90403

RE: Final results of the trial:

Double blind, placebo controlled, crossover pilot trial on the effect of Optically Modified Polyethylene Terephthalate Fiber mattress covers on sleep disturbances in patients with chronic back pain.
ClinicalTrials.gov Identifier: NCT00969540

Dear Mr. Casden:

The trial "Double blind, placebo controlled, crossover pilot trial on the effect of Optically Modified Polyethylene Terephthalate Fiber mattress covers on sleep disturbances in patients with chronic back pain" is now completed with all six enrolled subjects trial parameters analyzed.

The double blind, placebo controlled, crossover pilot trial evaluated the effect of Optically Modified Polyethylene Terephthalate Fiber mattress covers on sleep disturbances in patients with chronic back pain.

We assessed sleep quality in six patients with lower back pain as measured by Clinical Global Impression (CGI), sleep variables measured with actigraphy and exploratory objectives including the Pittsburgh Sleep Quality Index, visual analogue scale for pain, Clinical Global Impression of Sleep and Clinical Global Impression of Pain.

The total duration of the study for a participant was approximately 49 days, including 14 days of screening prior to treatment and 28 days of treatment interrupted by a wash-out phase of seven days. Subjects who met the initial screening criteria underwent actigraphy monitoring for a period of 14 days to record a baseline sleep pattern. Subjects were then offered, in this crossover double blind designed trial, either the active or the placebo garment mattress cover. 14 day actigraphy with use of the provided study material was performed followed by the crossover offering of the alternate garment for the next 14 days.

Here are some key findings:

- The median time spent awake at night after falling asleep was reduced by 18.3 minutes.
- Individuals spent 42 minutes less time sleeping, suggesting less need to sleep on Celliant (perhaps consolidating and improving sleep on the active garment).
- The median sleep efficiency improved by 2.6 %.
- Three out of six participants reported a subjective improvement of their sleep with the use of the active garment mattress cover as measured in the Clinical Global Impression scale.
- Two participants also reported that nocturnal back pain was better with the use of the active garment as measured in the Clinical Global Impression scale for pain.

Below is the summarized tabulated data for the six subjects who have completed the trial.

Average changes	Subject	Wake after sleep onset (min)	Total Sleep (min)	Number of nocturnal Awakenings	Sleep Efficiency (%)	Sleep Latency (min)
	1	-22.18	-14.53	-3.64	3.76	1.84
	2	7.71	-27.49	-1.81	-2.06	15.62
	3	-9.62	-89.61	5.63	-2.39	5.19
	4	-18.54	-13.77	-1.15	2.53	-10.92
	5	-46.01	-52.90	1.11	2.63	-15.50
	6	-1.27	-1.08	-0.50	-0.56	-0.40
	Average	-14.98	-33.23	-0.06	0.65	-0.70

Median values changes	Subject	Wake after sleep onset (min)	Total Sleep (min)	Number of nocturnal Awakenings	Sleep Efficiency (%)	Sleep Latency (min)
	1	-17.50	-4.50	-6.50	4.00	0.50
	2	-17.50	-26.00	-3.00	2.69	10.50
	3	-34.00	-138.00	5.00	3.93	0.00
	4	-21.00	-33.00	-2.00	2.27	-7.00
	5	-18.00	-59.00	-2.00	2.38	0.00
	6	-2.00	4.00	-1.00	0.29	0.00
	Average	-18.33	-42.75	-1.58	2.59	0.67

These results show tendencies toward the use of Celliant mattress covers in order to improve sleep but not lower back pain. The only participant without subjective or objective improvements had significant, acute chronic back pain at the time of enrollment. As the study is expanded, subjects with acute and severe back pain will not be admitted.

Other studies have shown that randomized, single-blinded, parallel-group studies evaluating structurally different mattresses, that bedding system differences can influence chronic low back pain and sleep (Bergholdt K et al 2008, Jacobson BH et al 2008, Jacobson BH et al 2002, Monsein M et al, 2000). A recent study showed improvements in mild back pain, sleep quality, and perceived stress in 59 patients after introduction of new bedding systems (Jacobson BH et al 2009).

Using the Wilcoxon Rank Sum Test, it is possible that with 12 additional subjects tested, more clear trends indicating the benefit of Celliant may emerge. Also, mild lower back pain is more likely to respond to Celliant than severe pain syndromes. Dr. Annabel Wang of the UCI Neurology Department will be continuing the project.

Regards,

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