



Center for Sleep Medicine
Department of Neurology
101 The City Drive S
Building 22C, Rte. 23
Orange, CA 92868
Tel: (714) 456-5105
Fax: (714) 456-7822

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

Reg: Interval results of the trial:

Double blind, placebo controlled, crossover pilot trial on the effect of Optically Modified Polyethylene Terephthalate Fiber mattress covers (AMBIENT COMFORT MATTRESS PAD –TOTAL BODY RENEWAL) 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 (AMBIENT COMFORT MATTRESS PAD –TOTAL BODY RENEWAL) on sleep disturbances in patients with chronic back pain.” is ongoing. We do have results from five of the six subjects enrolled in the study.

As you may recall, this double blind, placebo controlled, crossover pilot trial evaluates the effect of Optically Modified Polyethylene Terephthalate Fiber mattress covers (AMBIENT COMFORT MATTRESS PAD –TOTAL BODY RENEWAL) on sleep disturbances in patients with chronic back pain. We are in the process of assessing 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 is approximately 49 days, including 14 days of screening prior to treatment and 28 days of treatment interrupted by a wash-out phase of 7 days. Subjects who meet the initial screening criteria undergo actigraphy monitoring for a period of 14 days to record a baseline sleep pattern. Subjects are 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 is performed followed by the crossover offering of the alternate garment for the next 14 days.

The following points are of interest:

- The median time spent awake on the Celliant mattress cover at night after a subject had falling asleep was reduced by 21.5 minutes.
- The individuals spent less time sleeping on the Celliant mattress cover by 52 minutes, suggesting less need to sleep (and consolidating and improving the sleep on the active garment).

- Three 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 also reported that the 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 five subjects who have completed the trial (Data reported compare control mattress versus active cover).

Median values	Subject	Wake after sleep onset (min)	Total Sleep (min)	Number of nocturnal Awakenings	Sleep Efficiency (%)	Sleep Latency (min)
	1	-17.5	-4.5	-6.5	4.00	0.5
	2	-17.5	-26	-3	2.69	10.5
	3	-34	-138	5	3.93	0
	4	-21.0	-33.0	-2.0	2.27	-7.0
	5	-18.0	-59.0	-2.0	2.38	0.0
	Average	-21.6	-52.1	-1.7	3.05	0.8

Average	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
	Average	-17.73	-39.66	0.03	0.89	-0.76

I will add the data of the remaining subject once he/she completes the trial.

Marcel Hungs, M.D., Ph.D.

Assistant Professor of Clinical Neurology

Director, Center for Sleep Medicine at the University of California, Irvine

Diplomate of the American Board of Psychiatry and Neurology