

# Researchers find ramelteon may be useful for sleep problems after TBI

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Kessler researchers found preliminary evidence for the effectiveness of ramelteon for the treatment of sleep disturbances after traumatic brain injury (TBI). The article, "Pilot study on the effect of ramelteon on sleep disturbance after traumatic brain injury," was published ahead of print in the *Archives of Physical Medicine and Rehabilitation* on May 28, 2015. Authors are Anthony Lequerica, PhD, and Nancy Chiaravalloti, PhD, of Kessler Foundation, Neil Jasey, MD, of Kessler Institute for Rehabilitation, and Jaclyn Portelli Tremont, MA, of Robert Wood Johnson Medical School, Rutgers University.

Sleep problems affect 30% to 77% of individuals with [brain injury](#), affecting recovery and their ability to participate in rehabilitation. Mood disorders, fatigue and poor occupational outcomes are more common among people with sleep difficulties post TBI. Medications commonly used in treating sleep disturbance, including antidepressants, antihistamines and benzodiazepines, often have side effects that impair cognition. Ramelteon is a melatonin-agonist without the risks for dependence or addiction. Although it is approved for long-term treatment of insomnia, ramelteon had not been studied in this population.

Eighteen people with TBI were enrolled in this double-blind, placebo-controlled crossover trial. They completed five visits over nine weeks; evaluations included the neuropsychological testing, sleep variables, and mood measures. Participants were monitored using Actigraph, an electronic device worn on the wrist that measured the rest/activity cycle of the participants throughout the study, as well as by self report (sleep log). Outcomes measured included total sleep time (TST), sleep-onset latency (SOL) and cognitive functioning.

As in the non-TBI population, TST increased with three weeks of ramelteon 8 mg before bedtime, with maximal effectiveness achieved after one

week of treatment. The TBI population responded differently in terms of SOL, taking a few minutes longer to fall asleep on ramelteon. While statistically significant, the increase was less than 5 minutes on average and not considered clinically significant. Cognition improved after 3 weeks of treatment, evidenced by improvement on the CNSVS Neurocognitive Index derived from a neuropsychological battery delivered via computer. A significant improvement was noted on the executive functioning subtest with marginally significant improvement in reaction time.

"Ramelteon increased the total time asleep and seemed to bring more order or consistency to the sleep-wake cycles. These preliminary findings indicate that ramelteon may be useful for treating sleep-wake disturbances among individuals with TBI," said Dr. Lequerica, clinical research scientist in TBI Research at Kessler Foundation. "It may be optimal to begin ramelteon during acute care," he noted. "By addressing [sleep](#) issues before rehabilitation starts, we can optimize the person's ability to engage in rehabilitative therapies."

**More information:** *Archives of Physical Medicine and Rehabilitation*, [www.archives-pmr.org/article/S0003-9993\(15\)00423-2/pdf](http://www.archives-pmr.org/article/S0003-9993(15)00423-2/pdf)

Provided by Kessler Foundation

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