

About Clinical Trials

What is a clinical trial?

A clinical trial is a study to evaluate promising experimental treatments. They are designed to learn if new medications are safe, tolerable, and effective. A clinical trial differs from an observational study in which people are examined over time without receiving any experimental drugs or treatments

What is the Sleep & Ramelteon study?

Dr. Kaloyan Tanev of MGH is conducting a study of the medication Ramelteon in persons who have tested positive for the Huntington Disease (HD) gene, or persons who have received clinical diagnoses of Parkinson's Disease (PD) or Dementia with Lewy Bodies (DLB) and are complaining of trouble with sleep. This study is designed to determine the effects of 4 weeks of Ramelteon treatment on the sleep patterns of people with HD, PD, and DLB. The study also aims to look at the sleep patterns of caregivers of people with HD, PD, and DLB.

The 'who' and 'what' of the Sleep study

Who can participate in Sleep & Ramelteon?

In order to qualify for participation in the Sleep & Ramelteon study you must:

- Have trouble sleeping.
- Have either tested positive for the HD gene; OR, have been diagnosed with Parkinson's Disease or Dementia with Lewy Bodies.
- Be able to take oral medication and be willing to comply with study-specific procedures.
- Not be pregnant, lactating or intend to become pregnant during the time that you are participating in the study.

What are the study procedures?

If you are interested in participating in the Sleep & Ramelteon study you will first have a visit with the study doctor to determine if you are eligible to participate. If you qualify, then you will have a second visit to evaluate your general health, mood and movement.

During the study you will be asked to wear an actigraph, which records your sleep patterns, and keep a journal documenting the times you go to bed. You will be assigned randomly to receive either Ramelteon, or a pill that looks exactly like it but has no active ingredients (a placebo). You will continue to take the medication for a total of 8 weeks. There are 7 visits scheduled for this study to evaluate your general health and mood.

What are the risks associated with participation in Sleep & Ramelteon?

Some of the side effects noted for Ramelteon are fatigue, nausea, insomnia, upper respiratory infection, depression, pain in the joints, and taste and sense alteration. Further detail on these risks is explained in the consent form. Please ask Dr. Tanev, or the study coordinator if you have any questions or concerns.

What are the benefits to me if I decide to participate in Sleep & Ramelteon?

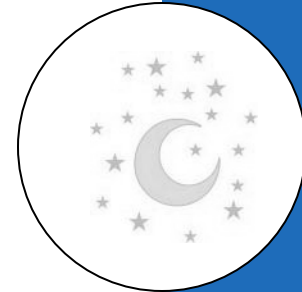
If you receive Ramelteon, the drug may help ameliorate your sleep wake cycle disturbances. Additionally, you and your caregiver will receive compensation for your participation in the study.

**How can I learn more about
Sleep & Ramelteon?**

If you think you might want to
participate in the Sleep &
Ramelteon study you can contact
the study's Principal Investigator,
Dr. Kaloyan Tanev:

617-726-7511
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SLEEP & RAMELTEON



**Ramelteon
Randomized Trial**

A clinical trial
conducted in the
Massachusetts
General Hospital
Department of
Neurology