Safety and Efficacy Study of Ramelteon in Subjects With Chronic Insomnia

This study has been completed.

Sponsor:
Takeda

Information provided by:
Takeda

ClinicalTrials.gov Identifier:
NCT00756002

First received: September 17, 2008
Last updated: May 31, 2010
Last verified: May 2010
History of Changes

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Results First Received: April 3, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Sleep Initiation and Maintenance Disorders
Interventions:	Drug: Ramelteon Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Subjects were enrolled at 19 sites in Europe and Russia from 21 August 2007 to 28 March 2008.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Sleep quality was assessed by postsleep questionnaires during a 21-day placebo run-in. Subjects were enrolled in Ramelteon or Placebo once-daily (QD) treatment group. 488 subjects entered placebo Run-in Period. 229 failed randomization criteria for entry into double-blind study medication phase of the study. 259 were randomized into the study.

Reporting Groups

	Description
Placebo QD	Oral Placebo was self-administered once-daily, 30 minutes prior to bedtime. The study medication consisted of identical film-coated pale orange-yellow tablets.
Ramelteon 4 mg QD	Ramelteon 4 mg tablets, self-administered once-daily, 30 minutes prior to bedtime. Study medication consisted of identical film-coated pale orange-yellow tablets.

Participant Flow for 3 periods

Period 1: Placebo Run-in

	Placebo QD	Ramelteon 4 mg QD
STARTED	**488**	**0**
COMPLETED	**259**	**0**
NOT COMPLETED	**229**	**0**

Period 2: Double-Blind Treatment Period

	Placebo QD	Ramelteon 4 mg QD
STARTED	**129**	**130**
COMPLETED	**114**	**115**
NOT COMPLETED	**15**	**15**
Lack of Efficacy	**1**	**1**
Lost to Follow-up	**0**	**1**
Withdrawal by Subject	**6**	**6**
Protocol Violation	**6**	**5**
Not Specified	**2**	**2**

Period 3: Placebo Run-out

	Placebo QD	Ramelteon 4 mg QD
STARTED	**114**	**0**
COMPLETED	**114**	**0**
NOT COMPLETED	**0**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Placebo QD	Oral Placebo was self-administered once-daily, 30 minutes prior to bedtime. The study medication consisted of identical film-coated pale orange-yellow tablets.

Ramelteon 4 mg QD	Ramelteon 4 mg tablets, self-administered once-daily, 30 minutes prior to bedtime. Study medication consisted of identical film-coated pale orange-yellow tablets.
Total	Total of all reporting groups

Baseline Measures

	Placebo QD	Ramelteon 4 mg QD	Total
Overall Participants Analyzed [Units: Participants]	**129**	**130**	**259**
Age [Units: Years] Mean (Standard Deviation)	**42.3 (12.28)**	**41.7 (11.85)**	**42.0 (12.05)**
Gender [Units: Participants]			
Female	**55**	**53**	**108**
Male	**74**	**77**	**151**
Race/Ethnicity, Customized [Units: Participants]			
Asian	**1**	**0**	**1**
Black or African American	**0**	**1**	**1**
White	**128**	**129**	**257**

Outcome Measures

Show All Outcome Measures

1. Primary: Mean Latency to Persistent Sleep Via Polysomnography (Nights 1-2). [Time Frame: Nights 1-2]
Show Outcome Measure 1

2. Secondary: Mean Latency to Persistent Sleep Via Polysomnography (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 2

3. Secondary: Mean Latency to Persistent Sleep Via Polysomnography (Nights 29-30). [Time Frame: Nights 29-30]
Show Outcome Measure 3

4. Secondary: Subjective Sleep Latency, Per Post-sleep Questionnaire (Nights 1-2). [Time Frame: Nights 1-2]
Show Outcome Measure 4

5. Secondary: Subjective Sleep Latency, Per Post-sleep Questionnaire (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 5

6. Secondary: Subjective Sleep Latency, Per Post-sleep Questionnaire (Nights 29-30). [Time Frame: Nights 29-30]
Show Outcome Measure 6

7. Secondary: Subjective Sleep Latency, Per Post-sleep Questionnaire (Week 2). [Time Frame: Week 2]
Show Outcome Measure 7

8. Secondary: Subjective Sleep Latency, Per Post-sleep Questionnaire (Week 4). [Time Frame: Week 4]
Show Outcome Measure 8

9. Secondary: Subjective Sleep Latency, Per Post-sleep Questionnaire (Week 5). [Time Frame: Week 5]
Show Outcome Measure 9

10. Secondary: Total Sleep Time, Per Polysomnography (Nights 1-2). [Time Frame: Nights 1-2]
Show Outcome Measure 10

11. Secondary: Total Sleep Time, Per Polysomnography (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 11

12. Secondary: Total Sleep Time, Per Polysomnography (Nights 29-30). [Time Frame: Nights 29-30]
Show Outcome Measure 12

13. Secondary: Subjective Total Sleep Time, Per Post-sleep Questionnaire (Nights 1-2). [Time Frame: Nights 1-2]
Show Outcome Measure 13

14. Secondary: Subjective Total Sleep Time, Per Post-sleep Questionnaire (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 14

15. Secondary: Subjective Total Sleep Time, Per Post-sleep Questionnaire (Nights 29-30). [Time Frame: Nights 29 -30]
Show Outcome Measure 15

16. Secondary: Subjective Total Sleep Time, Per Post-sleep Questionnaire (Week 2). [Time Frame: Week 2]
Show Outcome Measure 16

17. Secondary: Subjective Total Sleep Time, Per Post-sleep Questionnaire (Week 4). [Time Frame: Week 4]
Show Outcome Measure 17

18. Secondary: Subjective Total Sleep Time, Per Post-sleep Questionnaire (Week 5). [Time Frame: Week 5]
Show Outcome Measure 18

19. Secondary: Sleep Efficiency, Per Polysomnography (Nights 1-2). [Time Frame: Nights 1-2]
Show Outcome Measure 19

20. Secondary: Sleep Efficiency, Per Polysomnography (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 20

21. Secondary: Sleep Efficiency, Per Polysomnography (Nights 29-30). [Time Frame: Nights 29-30]
Show Outcome Measure 21

22. Secondary: Subjective Sleep Quality, Per Post-sleep Questionnaire (Nights 1-2). [Time Frame: Nights 1-2]
Show Outcome Measure 22

23. Secondary: Subjective Sleep Quality, Per Post-sleep Questionnaire (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 23

24. Secondary: Subjective Sleep Quality, Per Post-sleep Questionnaire (Nights 29-30). [Time Frame: Nights 29-30]
Show Outcome Measure 24

25. Secondary: Subjective Sleep Quality, Per Post-sleep Questionnaire (Week 2). [Time Frame: Week 2]
Show Outcome Measure 25

26. Secondary: Subjective Sleep Quality, Per Post-sleep Questionnaire (Week 4). [Time Frame: Week 4]
Show Outcome Measure 26

27. Secondary: Subjective Sleep Quality, Per Post-sleep Questionnaire (Week 5). [Time Frame: Week 5]
Show Outcome Measure 27

28. Secondary: Wake Time After Sleep Onset, Per Polysomnography (Nights 1-2). [Time Frame: Nights 1-2]

Show Outcome Measure 28

29. Secondary: Wake Time After Sleep Onset, Per Polysomnography (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 29

30. Secondary: Wake Time After Sleep Onset, Per Polysomnography (Nights 29-30). [Time Frame: Nights 29-30]
Show Outcome Measure 30

31. Secondary: Subjective Wake Time After Sleep Onset, Per Post-sleep Questionnaire (Nights 1-2). [Time Frame: Nights 1-2]
Show Outcome Measure 31

32. Secondary: Subjective Wake Time After Sleep Onset, Per Post-sleep Questionnaire (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 32

33. Secondary: Subjective Wake Time After Sleep Onset, Per Post-sleep Questionnaire (Nights 29-30). [Time Frame: Nights 29-30]
Show Outcome Measure 33

34. Secondary: Subjective Wake Time After Sleep Onset, Per Post-sleep Questionnaire (Week 2). [Time Frame: Week 2]
Show Outcome Measure 34

35. Secondary: Subjective Wake Time After Sleep Onset, Per Post-sleep Questionnaire (Week 4). [Time Frame: Week 4]
Show Outcome Measure 35

36. Secondary: Subjective Wake Time After Sleep Onset, Per Post-sleep Questionnaire (Week 5). [Time Frame: Week 5]
Show Outcome Measure 36

37. Secondary: Number of Awakenings After Persistent Sleep, Per Polysomnography (Nights 1-2). [Time Frame: Nights 1-2]
Show Outcome Measure 37

38. Secondary: Number of Awakenings After Persistent Sleep, Per Polysomnography (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 38

39. Secondary: Number of Awakenings After Persistent Sleep, Per Polysomnography (Nights 29-30). [Time Frame: Nights 29-30]
Show Outcome Measure 39

40. Secondary: Subjective Number of Awakenings, Per Post-sleep Questionnaire (Nights 1-2). [Time Frame: Nights 1-2]
Show Outcome Measure 40

41. Secondary: Subjective Number of Awakenings, Per Post-sleep Questionnaire (Nights 15-16). [Time Frame: Nights 15-16]
Show Outcome Measure 41

42. Secondary: Subjective Number of Awakenings, Per Post-sleep Questionnaire (Nights 29-30). [Time Frame: Nights 29-30]
Show Outcome Measure 42

43. Secondary: Subjective Number of Awakenings, Per Post-sleep Questionnaire (Week 2). [Time Frame: Week 2]
Show Outcome Measure 43

44. Secondary: Subjective Number of Awakenings, Per Post-sleep Questionnaire (Week 4). [Time Frame: Week 4]
Show Outcome Measure 44

45. Secondary: Subjective Number of Awakenings, Per Post-sleep Questionnaire (Week 5). [Time Frame: Week 5]
Show Outcome Measure 45

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: The sponsor can review results communications prior to public release; such communications can be embargoed for a period up to 150 days to permit actions necessary to preserve sponsor's intellectual property. Sponsor can request changes to the results communication only for the purpose of removing non study related information that is proprietary and confidential to sponsor. Sponsor can require delay of a results communication until the study has been completed at all participating sites.

Results Point of Contact:

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Responsible Party:	Sr VP, Clinical Science, Takeda Global Research & Development Center, Inc.
ClinicalTrials.gov Identifier:	NCT00756002 History of Changes
Other Study ID Numbers:	**01-06-TL-375-081** 2007-000403-15 (Registry Identifier: EudraCT) U1111-1115-2084 (Registry Identifier: WHO)
Study First Received:	September 17, 2008
Results First Received:	April 3, 2009
Last Updated:	May 31, 2010
Health Authority:	European Union: European Medicines Agency United Kingdom: Medicines and Healthcare Products Regulatory Agency

Finland: Finnish Medicines Agency
Germany: Federal Institute for Drugs and Medical Devices

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