

crispprd 1.0



## Abstract

**Grant Number:** 5R01NR004191-05

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**PI Title:** ASSOCIATE PROFESSOR

**Project Title:** MANAGEMENT OF EXCESSIVE DAYTIME SLEEPINESS IN NARCOLEPSY

**Abstract:** *DESCRIPTION: (Adapted from investigator's abstract) Many of the psychological and economic consequences of narcolepsy can be directly attributed to sleep attacks and excessive daytime sleepiness. Uncontrollable episodes of daytime sleep make driving difficult or hazardous, affect the individual's ability to continue an education and pursue a career, and often interfere with interpersonal relationships. Although treatment of narcolepsy can improve symptoms dramatically in some patients, up to a third of patients with narcolepsy obtain little or no benefit from current therapies. Studies have shown widespread dissatisfaction with current pharmacologic treatments; some patients report being undermedicated, that their symptoms are not adequately controlled with stimulant medications, and that they are not satisfied by with treatment regimes that require daytime naps and/or drug holidays. Differences between responders and non-responders and the bases for those differences are unknown. In addition, the identification of patients who are less likely to respond to stimulant medications, will allow clinicians to concentrate more efforts on improving treatment regimes for these patients. The identification of an instrument that is reliable, sensitive to treatment effects, and easy to administer would be of great value for assessing patient's responses to treatment. Thus, the aims of this proposed multicenter study are to: 1) Develop profiles of those patients who respond to stimulant medications and those who do not respond; and 2) evaluate two brief questionnaires (Narcolepsy Symptom Status Questionnaire and Epworth Sleepiness Scale) to see if they can be used to assess treatment efficacy in a clinical setting. Two groups of narcoleptic subjects (135 established patients and 85 newly diagnosed patients) will be recruited from 5 accredited sleep disorders centers. A profile of subjects who respond to*

*stimulant medications and those who do not will be developed from demographic data, symptom severity measures, and 24-hr ambulatory polysomnographic recordings made in the subject's usual environment. Compliance with stimulant medications will also be evaluated. In order to evaluate whether or not the NSSQ and ESS are sensitive to treatment effects, newly diagnosed subjects will be tested prior to starting stimulant medications, after 3 months of treatment and after one year of treatment.*

**Thesaurus Terms:**

*human therapy evaluation, narcolepsy, nervous system disorder chemotherapy, outcomes research, sleep disorder*

*REM sleep, cataplexy, central nervous system stimulant, longitudinal human study, nursing research, therapy compliance*

*adult human (19+), clinical research, human subject, polysomnography, questionnaire*

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