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Double-Blind, Placebo-Controlled, Parallel Group Study of VSOM-4.16 for Circadian Phase Advancement

Submission date 09/02/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 11/04/2006	**Overall study status** Completed	
Last Edited 09/10/2015	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MR-0513-VSOM-MS

Study information

Scientific Title
Double-Blind, Placebo-Controlled, Parallel Group Study of VSOM-4.16 for Circadian Phase Advancement

Study objectives
Use of VSOM-4.16 will decrease the time necessary for experimentally phase-advanced normal sleepers to fall asleep compared with placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval not yet received as of 11/04/2006

Study design
Randomized double blind

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Circadian phase advance

Interventions
VSOM-4.16 versus placebo. VSOM-4.16 is a device that electrically stimulates peripheral sensory receptors which appears to have an indirect effect of allowing individuals undergoing an advance in the phase of their sleep schedule to fall asleep faster.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Latency to persistent sleep onset

Key secondary outcome(s))
Polysomnographic measures:
1. Total sleep time
2. Sleep efficiency
3. Number of awakenings
4. Wake after sleep onset
5. Minutes in each sleep stage (1, 2, 3-4 non-rapid eye movement [NREM] and REM)
6. Minutes of slow wave sleep during each quartile of the night

Subjective measures:
1. Ratings of sleep latency
2. Total sleep time
3. Sleep quality
4. Number of awakenings

5. Quality of sleep
6. Level of alertness in the morning

Completion date
20/08/2006

Eligibility

Key inclusion criteria
1. Males and females, ages 21-60 (inclusive)
2. Able and willing to provide written informed consent
3. Reported habitual bedtime between 2100 and 0100 hours, which does not vary by more than one hour at least five nights per week (for example if the habitual bedtime is 12:00 then the time to bed should be between 11:30 and 12:30)
4. Reported habitual nightly sleep duration of 6.5 to 8.5 hours
5. Habitual bedtime and sleep duration consistent with reported habitual bedtime and sleep duration as determined by sleep log and 7 to 14 days of actigraphic monitoring

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participation in a study of investigational or marketed drugs or devices during the 30-day period before the start of the study or during the study
2. Clinically significant medical or psychiatric condition
3. Probable diagnosis of a current sleep disorder including but not limited to insomnia, sleep apnea, restless legs syndrome, or periodic limb movement disorder
4. Positive urine drug screen at any visit prior to randomization
5. Positive alcohol saliva test at any visit prior to randomization
6. History of current or recent (e.g. within past five years) alcohol, narcotic or any other drug abuse as defined by the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association, Fourth Edition (DSM-IV)
7. Currently works night shift or rotating shift
8. Travel or planned travel across more than two time zones within one week prior to randomization
9. Use of any medication that, in the opinion of the investigator, may alter sleep or wakefulness
10. Mean screening (multiple sleep latency test [MSLT] of <8 minutes across five naps, or one sleep onset rapid eye movement [REM] period on any MSLT nap
11. Sleep efficiency >94% per screening polysomnography (PSG)
12. An apnea/hypopnea index >10 per hour, or a periodic limb movement with arousal index >10 per hour on the screening PSG
13. Consumption of more than 14 alcoholic drinks per week, or the recent consumption of more

than four alcoholic drinks in one night
14. Typically consumes more than five caffeinated beverages per day
15. Regular use of tobacco products (i.e. more than one pack of cigarettes per day)
16. Pregnancy (will confirm absence of pregnancy with a urine or serum pregnancy test in women of child bearing age)
17. Presence of a pacemaker
18. Presence of epilepsy or other uncontrolled medical conditions
19. Prior participation in a VSOM protocol
20. History of vestibular disorders (such as vertigo)

Date of first enrolment
20/02/2006

Date of final enrolment
20/08/2006

Locations

Countries of recruitment
United States of America

Study participating centre
Box 3309
North Carolina
United States of America
27710

Sponsor information

Organisation
Duke University Medical Center (USA)

ROR
https://ror.org/03njmea73

Funder(s)

Funder type
University/education

Funder Name
Duke University Medical Center

Funder Name
Harvard Medical School

Alternative Name(s)
Harvard Med School, HMS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Funder Name
Clinilabs Inc.

Funder Name
Rush University Medical Center

Funder Name
University of Arizona College of Medicine

Funder Name
Respironics Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration