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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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North Carolina
United States of America
27710

## 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

Αll

#### 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