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Trial record **1 of 1** for: C10953/3067/ES/MN

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Study to Evaluate the Efficacy and Safety of Armodafinil as Treatment for Patients With Excessive Sleepiness Associated With Mild or Moderate Closed Traumatic Brain Injury

This study has been terminated.

(Study has been stopped by sponsor decision.)

Sponsor:
Cephalon

Information provided by (Responsible Party):
Teva Pharmaceutical Industries (Cephalon)

ClinicalTrials.gov Identifier:
NCT00893789

First received: May 4, 2009
Last updated: August 14, 2013
Last verified: August 2013
History of Changes

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Purpose

The primary objective of the study is to determine whether armodafinil treatment is more effective than placebo treatment in patients with excessive sleepiness associated with mild or moderate closed traumatic brain injury (TBI).

Condition	Intervention	Phase
Traumatic Brain Injury	Drug: Armodafinil Other: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of Armodafinil (50, 150, and 250 mg/Day) as Treatment for Patients With Excessive Sleepiness Associated With Mild or Moderate Closed Traumatic Brain Injury

Resource links provided by NLM:

MedlinePlus related topics: Traumatic Brain Injury

Drug Information available for: Modafinil Armodafinil

U.S. FDA Resources

Further study details as provided by Teva Pharmaceutical Industries:

Primary Outcome Measures:

- Change From Baseline in Multiple Sleep Latency Test (MSLT) at Endpoint (Last Postbaseline Observation Up to Week 12)
  [Time Frame: Baseline, last postbaseline observation up to Week 12] [Designated as safety issue: No]

  The MSLT is an objective assessment of sleepiness that measures the likelihood of falling asleep. Four 20-minute (maximum) MSLT naps were performed at 0900, 1100, 1300, and 1500. The participant, dressed in nonconstricting clothes, was instructed to lie quietly and attempt sleep. Each MSLT nap continued until: (a) 3 consecutive 30-second epochs of stage 1 sleep were reached or (b) any single, 30-second epoch of stage 2, 3, 4, or rapid eye movement (REM) sleep was reached. Sleep latency for each nap and average sleep latency for the 4 naps were tabulated. According to clinical protocol for the MSLT, each nap was terminated after 20 minutes if no sleep occurred. If a participant did not fall asleep in 20 minutes, his/her sleep latency for that nap was set to 20 minutes. Sleep latency was measured as the elapsed time from lights-out

to the first epoch scored as sleep. With a 30-second scoring epoch, this criterion was reached when sleep occupied at least 16 seconds of any epoch.

- Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Endpoint (Last Postbaseline Observation Up to Week 12) [Time Frame: Last postbaseline observation up to Week 12] [Designated as safety issue: No]

  The CGI-C is the clinician's rating of disease severity as compared with pretreatment, assessed by the Clinical Global Impression of Severity (CGI-S). Severity of illness, as related to excessive sleepiness, was assessed at baseline by the CGI-S, which consists of 7 categories: normal-shows no sign of illness, borderline ill, mildly (slightly) ill, moderately ill, markedly ill, severely ill, and among the most extremely ill. The clinician assessed the change from baseline in the participant's condition, as related to excessive sleepiness, in response to treatment. The CGI-C uses the following 7 categories and scoring assignments: very much improved, much improved, minimally improved, no change, minimally worse, much worse, and very much worse. Responders were defined as those participants who were considered much or very much improved on the CGI-C. Those in all other categories of the CGI-C were considered nonresponders.

Secondary Outcome Measures:

- Change From Baseline in Mean Sleep Latency From the MSLT at Weeks 4, 8, and 12 [Time Frame: Baseline, Weeks 4, 8, and 12] [Designated as safety issue: No]

  The MSLT is an objective assessment of sleepiness that measures the likelihood of falling asleep. Four 20-minute (maximum) MSLT naps were performed at 0900, 1100, 1300, and 1500. The participant, dressed in nonconstricting clothes, was instructed to lie quietly and attempt sleep. Each MSLT nap continued until: (a) 3 consecutive 30-second epochs of stage 1 sleep were reached or (b) any single, 30-second epoch of stage 2, 3, 4, or rapid eye movement (REM) sleep was reached. Sleep latency for each nap and average sleep latency for the 4 naps were tabulated. According to clinical protocol for the MSLT, each nap was terminated after 20 minutes if no sleep occurred. Sleep latency was measured as the elapsed time from lights-out to the first epoch scored as sleep. With a 30-second scoring epoch, this criterion was reached when sleep occupied at least 16 seconds of any epoch.

- Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Weeks 2, 4, 8, and 12 [Time Frame: Weeks 2, 4, 8, and 12] [Designated as safety issue: No]

  The CGI-C is the clinician's rating of disease severity as compared with pretreatment, assessed by the Clinical Global Impression of Severity (CGI-S). Severity of illness, as related to excessive sleepiness, was assessed at baseline by the CGI-S, which consists of 7 categories: normal-shows no sign of illness, borderline ill, mildly (slightly) ill, moderately ill, markedly ill, severely ill, and among the most extremely ill. The clinician assessed the change from baseline in the participant's condition, as related to excessive sleepiness, in response to treatment. The CGI-C uses the following 7 categories and scoring assignments: very much improved, much improved, minimally improved, no change, minimally worse, much worse, and very much worse. Responders were defined as those participants who were considered much or very much improved on the CGI-C. Those in all other categories of the CGI-C were considered nonresponders.

- Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Total Score At Weeks 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to Week 12) [Time Frame: Weeks 4, 8, 12 and Endpoint (last postbaseline observation up to Week 12)] [Designated as safety issue: No]

  The TBI-WIS is a validated participant-rated instrument for assessing a participant's functional ability after TBI and the functional demands of their job. The assessment consists of 36 questions to which the participant responded with a "true" or "not true" answer. To score the questionnaire, the number of "true" responses is counted: if < 2, the risk is low; 2 to 23, the risk is medium; and >23, the risk is high, for work instability. Score range is 0 (lowest risk for work instability) to 36 (highest risk for work instability).

- Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 12 and Endpoint (Last Postbaseline Observation Up to Week 12) [Time Frame: Baseline, Week 12, Endpoint (last postbaseline observation, up to Week 12)] [Designated as safety issue: No]

  The patient's evaluation of excessive daytime sleepiness was measured by the ESS. The ESS score is based on responses to questions referring to 8 everyday situations (eg, sitting and reading, talking to someone, being stopped in traffic) and reflects a patient's propensity to fall asleep in those situations. The ESS score is derived from the sum of the values from questions corresponding to the 8 situations. Scores for the ESS range from 0 to 24, with a higher score indicating a greater daytime sleepiness. This test was self-administered.

- Percentage of Participants Answering "No" to All Questions on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to Week 12) [Time Frame: Weeks 4, 8, 12 and Endpoint (last postbaseline observation up to Week 12)] [Designated as safety issue: Yes]

  The C-SSRS captures occurrence, severity, and frequency of suicide-related thoughts and behaviors since last visit (SLV). The number of participants answering 'no' to all 9 yes/no questions about suicidal behaviors, ideations, and acts are presented. Questions included the presence of the following: a wish to be dead; nonspecific active suicidal thoughts; actual suicide attempt; non-suicidal self-injurious behavior; interrupted attempt; aborted attempt; suicidal behavior; preparatory suicidal acts or behavior; and completed suicide.

- Change From Baseline in the Total Score From the Self-Reported Hamilton Depression Rating Scale, 6 Item Version (S-HAM-D6) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks) [Time Frame: Baseline, Weeks 2, 4, 8, 12, and Endpoint (last postbaseline observation up to 12 weeks)] [Designated as safety issue: Yes]

The self-reported S-HAM-D6 is a validated scale developed from the core depressive items of the 17 Item Hamilton Depression Inventory (HAM -D17). The HAM-D6 (Items 1, 2, 7, 8, 10, 13 from the 17-item HAMD) evaluates "core" symptoms of Major Depressive Disorder (MDD). The assessment consists of 6 items representing depressed mood, guilt, work and activities, retardation, psychic anxiety, and general somatic symptoms. Each item is evaluated and scored using either a 5-point scale (e.g. absent, mild, moderate, severe, very severe) or a 3-point scale (e.g. absent, mild, marked). Total scores range from 0 (normal) to 22 (severe). Scores greater than 12 indicate moderate to severe depression and scores less than 12 indicate mild depression.

- Change From Baseline in the Total Sleep Time As Assessed by Nocturnal Polysomnography (NPSG) at Weeks 2, 4, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks) [Time Frame: Baseline, Weeks 2, 4, 12, and Endpoint (last postbaseline observation up to 12 weeks)] [Designated as safety issue: Yes]

  NPSG continuously records normal and abnormal physiological activity during an entire night. It documents the adequacy of sleep, including the frequency, duration, and total amounts of stage 1-2, stage 3-4 (slow wave sleep), and rapid eye movement (REM) sleep.

- Plasma Concentrations of Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) at Weeks 4, 8, and 12 (or Last Postbaseline Observation Up to Week 12) [Time Frame: Weeks 4, 8, and 12 (or last postbaseline observation, up to Week 12)] [Designated as safety issue: No]

  To evaluate the impact of treatment with armodafinil on the pharmacokinetics of selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs) (as appropriate), plasma concentrations at weeks 4, 8, and 12 (or last postbaseline observation) were to be assessed.

- Concomitant Medication Usage In ≥5% of Participants Throughout the Study [Time Frame: Screening through Week 12] [Designated as safety issue: Yes]

  Therapeutic classification of concomitant medications used by ≥5% of participants throughout the study. Participants are counted only once in each therapeutic class category. Medications were included in the table if the proportion of participants in the combined armodafinil treatment group was ≥5%.

- Number of Participants With Adverse Events (AEs), Serious AEs (SAEs), Deaths, and Withdrawals Due to AEs [Time Frame: Screening through Week 12] [Designated as safety issue: Yes]

  AE=any untoward medical occurrence in a patient that develops or worsens in severity during the conduct of the clinical study of a pharmaceutical product and does not necessarily have a causal relationship to the study drug. SAE=any AE that resulted in any of the following: death; a life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; a congenital anomaly or birth defect; an important medical event that required medical intervention to prevent 1 of the outcomes listed in this definition. Treatment-related AEs=definite, probable, possible, or missing relationship. Protocol-defined AEs=treatment-emergent adverse events associated with skin rash, hypersensitivity reaction, emergent suicidal ideation or suicide attempt, depression, psychosis (including hypomanic or manic episode), and seizure or suspected seizure were considered to be of potential clinical importance.

- Number of Participants With Clinically Significant Abnormal Postbaseline Serum Chemistry Values [Time Frame: Baseline, last postbaseline observation up to Week 12] [Designated as safety issue: Yes]

  Normal ranges for serum chemistry values: blood urea nitrogen (BUN), 1.43 - 8.57 mmol/L; uric acid, 124.91 - 493.68 µmol/L; aspartate aminotransferase (AST), 11 - 36 U/L; gamma-glutamyl transpeptidase (GGT), 10 - 61 U/L; total bilirubin, 3.42 - 20.52 µmol/L.

- Number of Participants With Clinically Significant Abnormal Postbaseline Hematology Values [Time Frame: Baseline, last postbaseline observation up to Week 12] [Designated as safety issue: Yes]

  Normal ranges for hematology values: white blood cell (WBC) count, 3.8 - 10.7 x 10^9/L; absolute neutrophil count (ANC), 1.96 - 7.23 x 10^9/L. Participants may have had more than one clinically significant abnormal value.

- Number of Participants With Clinically Significant Abnormal Postbaseline Urinalysis Values [Time Frame: Baseline, last postbaseline observation up to Week 12] [Designated as safety issue: Yes]

  Participants with at least one clinically significant postbaseline urinalysis abnormality, specifically presented is blood (hemoglobin) in urine >=2 units increase from baseline.

- Number of Participants With Clinically Significant Abnormal Vital Sign Values [Time Frame: Baseline, last postbaseline observation up to Week 12] [Designated as safety issue: Yes]

  Criteria for clinically significant abnormal vital signs values: heart rate, ≤50 beats per minute (bpm) and decrease from baseline of ≥15 bpm; sitting systolic blood pressure, ≤90 mm Hg and decrease from baseline of ≥20 mm Hg; sitting diastolic blood pressure, ≤50 mm Hg and decrease from baseline of ≥15 mm Hg.

- Number of Participants With Notable Blood Pressure Values Per World Health Organization Criteria [Time Frame: Baseline, last postbaseline observation up to Week 12] [Designated as safety issue: Yes]

  Criteria for World Health Organization (WHO) notable blood pressure (BP) values: systolic blood pressure, ≥140 mm Hg plus increase of ≥10% from baseline; diastolic blood pressure, ≥90 mm Hg plus increase of ≥10% from baseline.

- Electrocardiogram (ECG) Findings Shifts From Baseline to Overall [Time Frame: Baseline through Endpoint (last postbaseline observation, up to Week 12)] [Designated as safety issue: Yes]

  Number of participants with shifts from normal/abnormal 12-lead ECG findings at baseline (BL) to (→) normal/abnormal findings overall are presented. For overall, the worst postbaseline finding (the abnormal finding if there are both normal and abnormal findings) for the participant between baseline and endpoint (defined as last postbaseline observation, up to Week 12) is summarized. Shifts (normal and abnormal) from baseline to overall are summarized using participant counts. Any ECG finding that was judged by the investigator as a clinically meaningful change (worsening) compared to baseline was recorded as an adverse event.

- Physical Examination Findings Shifts From Baseline to Endpoint (Last Postbaseline Observation, up to Week 12) [Time Frame: Baseline through Endpoint (last postbaseline observation, up to Week 12)] [Designated as safety issue: Yes]

  Number of participants with shifts from normal/abnormal physical examination findings at baseline (BL) to (→) normal/abnormal findings at endpoint (EP, defined as last postbaseline observation, up to Week 12). Shifts (normal and abnormal) from baseline to endpoint are summarized using participant counts for each physical examination category. A newly diagnosed finding was defined as being normal or missing at baseline and abnormal at least once during the study. Any physical examination finding that was judged by the investigator as a clinically significant change (worsening) compared to a baseline value was considered an adverse event. HEENT=head, eyes, ears, nose, throat.

Enrollment: 117
Study Start Date: April 2009
Study Completion Date: January 2011
Primary Completion Date: January 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Armodafinil 50 mg/day	Drug: Armodafinil Armodafinil 50 mg/day
Experimental: 2 Armodafinil 150 mg/day	Drug: Armodafinil Armodafinil 150 mg/day
Experimental: 3 Armodafinil 250 mg/day	Drug: Armodafinil Armodafinil 250 mg/day
Placebo Comparator: 4 Placebo	Other: Placebo Placebo

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:

- The patient had a mild (Glasgow Coma Scale [GCS] score 13-15) or moderate (GCS score 9-12) closed TBI at the time of the injury, and the injury occurred 1 to 10 years prior to screening.
- The patient had a Glasgow Outcome Scale score of 5 at the screening visit.
- The patient had an Epworth Sleepiness Scale (ESS) score of at least 10 at screening.
- The patient had a mean sleep latency on the Multiple Sleep Latency Test (MSLT) (average of 4 naps) of less than 8 minutes at baseline.
- The patient had a Clinical Global Impression of Severity of Illness (CGI-S) rating relating to their excessive sleepiness of 4 or more at the screening and baseline visits.
- The patient had a complaint of excessive sleepiness (at least 5 days/week on average) for at least 3 months, and the excessive sleepiness began within 12 months of the TBI.
- Written informed consent was obtained.
- The patient was a man or woman of any ethnic origin 18 to 65 years of age.
- If admitted to an inpatient treatment facility, the patient was discharged at least 1 month prior to the screening visit.
- The patient did not have any medical or psychiatric disorders that could account for the excessive sleepiness.
- Women of childbearing potential (not surgically sterile or 2 years postmenopausal), used a medically accepted method of contraception, and continued use of one of these methods for the duration of the study (and for 30 days after participation in the study). Acceptable methods of

contraception included: abstinence, barrier method with spermicide, steroidal contraceptive (oral, transdermal, implanted, and injected) in conjunction with a barrier method, or intrauterine device (IUD).

- The patient was in otherwise good health, as judged by the investigator, on the basis of a medical and psychiatric history, physical examination, electrocardiogram (ECG), serum chemistry, hematology, and urinalysis.
- The patient was willing and able to comply with study restrictions and to attend regularly scheduled clinic visits as specified in this protocol.
- The patient had a Mini Mental State Examination (MMSE) score of more than 26 at the screening visit.
- The patient was on stable dosages of medications (allowed by the protocol) for a minimum of 3 months (selective serotonin reuptake inhibitors [SSRIs] and serotonin-norepinephrine reuptake inhibitors [SNRIs]), 8 weeks (contraceptives), or 4 weeks (all other allowed medication) before the screening visit and was not likely to require a change in therapy for at least 12 weeks on the basis of the investigators' assessment.
- The patient had a habitual bedtime between 2100 and 2400.
- The patient had no other head injuries that, based on medical record documentation or history from the patient and reliable informant (if available), were temporally related to the onset or to any worsening of excessive sleepiness.
- The patient had no other head injury fulfilling the criteria for TBI within ±1 year of the TBI identified according to criterion (a1).

Exclusion Criteria:

- The patient had a history of 2 or more episodes of transient loss of consciousness (LOC) without clear medical explanation, or had a history of known or suspected pseudo seizure (psychogenic seizure). Patients with a history of seizure or epilepsy may have been eligible following discussion with the medical monitor.
- The patient required, or was likely to require, treatment with anticonvulsant medication during the study, or had taken anticonvulsant medication within 6 months before the screening visit.
- The patient had an unstable or uncontrolled medical (including illnesses related to the cardiovascular [including patients with a history of left ventricular hypertrophy or in patients with mitral valve prolapse who had experienced the mitral valve prolapse syndrome], renal, or hepatic systems or surgical) condition (treated or untreated) or was not a suitable candidate for treatment with armodafinil, as judged by the investigator.
- The patient had neurosurgery involving the brain or brainstem.
- The patient had a history of schizophrenia, bipolar disorder, psychotic depression, or other psychotic episode.
- The patient had any current Axis I disorder (including depression and posttraumatic stress disorder [PTSD]), as assessed by Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (SCID). The patient had any Axis II disorder (as assessed by SCID) that, in the opinion of the investigator, would affect patient participation in the study or full compliance with study procedures.
- The patient had a history of, or currently met The International Classification of Sleep Disorders, Edition 2 (ICSD 2) (American Academy of Sleep Medicine 2005) criteria for narcolepsy, obstructive sleep apnea/hypopnea syndrome (OSAHS), shift work sleep disorder (SWSD), or any other sleep disorder associated with excessive daytime sleepiness; or the patient had a history of idiopathic hypersomnia, insomnia (requiring treatment), or sleep disorder before the development of the TBI.
- The patient had 85% or less sleep efficiency (sleep duration ÷ time in bed x 100%) as determined from nocturnal polysomnography (NPSG).
- The patient had any disorder that may interfere with drug absorption, distribution, metabolism, or excretion.
- The patient used any medications, including over-the-counter (OTC) medicines disallowed by the protocol, within 7 days or 5 half lives (medication or its active metabolites), whichever was longer, before the screening visit.
- The patient had a need for chronic pain medications.
- In the judgment of the investigator, the patient had a clinically significant deviation from normal in the physical examination.
- In the judgment of the investigator, the patient had any clinically significant ECG finding.
- The patient had a diagnosis of any type of dementia.
- The patient had a history of suicidal ideation (considered by the investigator to be of current clinical significance), or was currently suicidal.
- The patient had a known hypersensitivity to armodafinil, racemic modafinil, or any component of the study drug tablets. Armodafinil tablets contain the following inactive ingredients: croscarmellose sodium, lactose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinized starch.
- The patient had a history of any clinically significant cutaneous drug reaction, or a history of clinically significant hypersensitivity reaction, including multiple allergies or drug reactions.
- The patient had a clinical laboratory test value(s) outside the range(s) specified by protocol (or any other clinically significant laboratory abnormality), and the medical monitor had not provided written approval for study participation.
- The patient had a history (within the past 5 years) of alcohol, narcotic, or any other drug abuse (with the exception of nicotine) as defined by the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association, 4th Edition, Text Revision (DSM-IV-TR), or the patient had current evidence of substance use, without medical explanation, confirmed by results of a urine drug screen (UDS).
- The patient had taken armodafinil, modafinil or other stimulant medication for excessive sleepiness within 1 month of the screening visit.
- The patient was a pregnant or lactating woman. (Any women becoming pregnant during the study were to be withdrawn from the study.)
- The patient was known to have tested positive for human immunodeficiency virus (HIV).
- The patient consumed an average of more than 600 mg of caffeine per day, including coffee, tea and/or other caffeine-containing beverages or food.
- The patient used any investigational drug within 1 month before the screening visit.

- The patient was receiving workmen's compensation or was in active litigation with regard to TBI.
- The patient had a self-reported Hamilton Depression Rating Scale, 6 Item Version (S HAM D6) score of more than 4 at the screening visit.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00893789

Hide Study Locations

Locations

United States, Alabama

Sleep Disorders Center of Alabama
Birmingham, Alabama, United States, 35213

United States, Arizona

REM Medical Clinical Research
Tucson, Arizona, United States, 85712

United States, Arkansas

Central Arkansas Research
Hot Springs, Arkansas, United States, 71913

Clinical Study Centers, LLC
Little Rock, Arkansas, United States, 72205

United States, California

Pacific Sleep Medicine
Fountain Valley, California, United States, 92708

Pacific Sleep Medicine Services, Inc.
Los Angeles, California, United States, 90048

Southwestern Research, Inc.
Pasadena, California, United States, 91106

Pacific Sleep Medicine Services, Inc.
Redlands, California, United States, 92373

VA Northern California Health Care System
Sacramento, California, United States, 94553

Avastra Clinical Trials, Inc.
San Diego, California, United States, 92121

Pacific Research Network, Inc.
San Diego, California, United States, 92103

VA San Diego Healthcare System
San Diego, California, United States, 92161

Southwestern Research, Inc.
Santa Ana, California, United States, 92705

St. Johns Medical Plaza Sleep Disorders Center
Santa Monica, California, United States, 90404

United States, Connecticut

Gaylord Hospital
Wallingford, Connecticut, United States, 06492

United States, Florida

MD Clinical
Hallandale Beach, Florida, United States, 33009

Miami Research Associates
Miami, Florida, United States, 33173

Compass Research, LLC
Orlando, Florida, United States, 32806

Broward Research Group
Pembrooke Pines, Florida, United States, 33026

Florida Sleep Institute
Spring Hill, Florida, United States, 34609

Clinical Research Group of St. Petersburg
St. Petersburg, Florida, United States, 33707

SomnoMedics
Tampa, Florida, United States, 33607

United States, Georgia

Sleep Disorders Center of GA
Atlanta, Georgia, United States, 30342

Neurotrials Research
Atlanta, Georgia, United States, 30342

Sleep Disorders Center of Georgia
Gainesville, Georgia, United States, 30501

Sleepmed of Central GA
Macon, Georgia, United States, 31201

Georgia Neurology & Sleep Medicine Associates
Suwanee, Georgia, United States, 30024

United States, Indiana

Midwest Neurology, Inc.
Danville, Indiana, United States, 46122

Fort Wayne Neurological Center
Fort Wayne, Indiana, United States, 46804

Goldpoint Clinical Research, LLC
Indianapolis, Indiana, United States, 46260

Rehabilitation Associates
Indianapolis, Indiana, United States, 46250

United States, Iowa

University of Iowa Hospitals
Iowa City, Iowa, United States, 52242

United States, Kansas

Vince and Associates Clinical Research
Overland Park, Kansas, United States, 66212

United States, Kentucky

Community Research
Crestview, Kentucky, United States, 45217

Kentucky Research Group
Louisville, Kentucky, United States, 40217

United States, Maryland

Center for Sleep and Wake Disorders
Chevy Chase, Maryland, United States, 20815

United States, Massachusetts

McLean Hospital
Belmont, Massachusetts, United States, 02478

Sleep Health Centers
Framingham, Massachusetts, United States, 01701

United States, Mississippi

The Center for Sleep Medicine
Hattiesburg, Mississippi, United States, 39402

United States, Missouri

Clayton Sleep Institute
St. Louis, Missouri, United States, 63143

United States, Nebraska

Somnos Laboratories
Lincoln, Nebraska, United States, 68510

United States, New York

Clinilabs, Inc
New York, New York, United States, 10019

Avastra Eastern Sleep Medicine Centers of Western NY
West Seneca, New York, United States, 14224

United States, North Carolina

Duke University Medical Center
Durham, North Carolina, United States, 27710

Wake Forest University Health Sciences
Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Tri State Sleep Disorders Center
Cincinnati, Ohio, United States, 45246

North Star Medical Research, LLC
Middleburg Heights, Ohio, United States, 44130

Mercy St. Anne Sleep Disorder Center
Toledo, Ohio, United States, 43623

United States, Oklahoma

Lynn Health Science Institute
Oklahoma City, Oklahoma, United States, 73112

United States, Oregon

Avastra Clinical Trials
Tigard, Oregon, United States, 97223

United States, Pennsylvania

Sleep Lab of Northeastern PA
Clarks Summit, Pennsylvania, United States, 18411

Consolidated Clinical Trials
Pittsburgh, Pennsylvania, United States, 15221

United States, South Carolina

SleepMed of South Carolina
Columbia, South Carolina, United States, 29201

United States, Tennessee

Mid-South Neurology Clinic, PLLC
Germantown, Tennessee, United States, 38139

United States, Texas

FutureSearch Trials of Neurology
Austin, Texas, United States, 78756

UT Southwestern Medical Center at Dallas
Dallas, Texas, United States, 75235

Houston Sleep Center
Houston, Texas, United States, 77063

Baylor College of Medicine
Houston, Texas, United States, 77030

Sleep Therapy and Research Center
San Antonio, Texas, United States, 78229

United States, Utah

Avastra Clinical Trials
Midvale, Utah, United States, 84047

United States, Virginia

McGuire Research Institute
Richmond, Virginia, United States, 23249

United States, Wisconsin

Sleep Wellness Institute
West Allis, Wisconsin, United States, 53227

Spain

Cephalon Investigational Site
Barcelona, Spain

Cephalon Investigational Site
Madrid, Spain, 28036

Virgin Islands (U.S.)

Global Research Associates
St. Thomas, Virgin Islands (U.S.), 00802

Sponsors and Collaborators

Cephalon

Investigators

Study Director: Sponsor's Medical Expert, MD Cephalon, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

More Information

No publications provided by Teva Pharmaceutical Industries

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Menn SJ, Yang R, Lankford A. Armodafinil for the treatment of excessive sleepiness associated with mild or moderate closed traumatic brain injury: a 12-week, randomized, double-blind study followed by a 12-month open-label extension. J Clin Sleep Med. 2014 Nov 15;10(11):1181-91. doi: 10.5664/jcsm.4196.

Responsible Party:	Teva Pharmaceutical Industries (Cephalon)
ClinicalTrials.gov Identifier:	NCT00893789 History of Changes
Other Study ID Numbers:	**C10953/3067/ES/MN**
Study First Received:	May 4, 2009
Results First Received:	May 9, 2013
Last Updated:	August 14, 2013
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Brain Injuries	Modafinil
Brain Diseases	Central Nervous System Agents
Central Nervous System Diseases	Central Nervous System Stimulants
Craniocerebral Trauma	Pharmacologic Actions
Nervous System Diseases	Physiological Effects of Drugs
Trauma, Nervous System	Therapeutic Uses
Wounds and Injuries	Wakefulness-Promoting Agents
Armodafinil	

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Trial record **1 of 1** for: C10953/3067

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Study to Evaluate the Efficacy and Safety of Armodafinil as Treatment for Patients With Excessive Sleepiness Associated With Mild or Moderate Closed Traumatic Brain Injury

This study has been terminated.

(Study has been stopped by sponsor decision.)

Sponsor:
Cephalon

Information provided by (Responsible Party):
Teva Pharmaceutical Industries (Cephalon)

ClinicalTrials.gov Identifier:
NCT00893789

First received: May 4, 2009
Last updated: August 14, 2013
Last verified: August 2013
History of Changes

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Results First Received: May 9, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Traumatic Brain Injury
Interventions:	Drug: Armodafinil Other: 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
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Participant Flow: Overall Study

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day
STARTED	29	30	29	29
Safety Analysis Set (SAS)	29 [1]	30	29	29
Full Analysis Set (FAS)	29 [2]	29	28	27
COMPLETED	23	26	22	16
NOT COMPLETED	6	4	7	13
Withdrawal by Subject	3	1	3	1
Noncompliance With Study Drug	1	0	1	2
Noncompliance With Study Procedures	1	0	0	0
Taking Excluded Concomitant Medication	1	0	1	0
Adverse Event	0	2	1	5
Protocol Violation	0	1	1	4
Lost to Follow-up	0	0	0	1

[1] SAS = all participants who received 1 or more doses of study drug.
[2] FAS = participants in the safety analysis set with ≥1 postbaseline primary efficacy assessment.

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	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)
Total	Total of all reporting groups

Baseline Measures

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day	Total
Number of Participants [units: participants]	29	30	29	29	117
Age [units: years] Mean (Standard Deviation)	30.2 (11.02)	33.2 (9.31)	32.3 (10.81)	29.4 (11.07)	31.3 (10.54)

Gender [units: participants]					
Female	**14**	**13**	**13**	**13**	**53**
Male	**15**	**17**	**16**	**16**	**64**
Race/Ethnicity, Customized [units: participants]					
American Indian or Alaska Native	**0**	**0**	**1**	**0**	**1**
Asian	**1**	**0**	**0**	**1**	**2**
Black or African American	**2**	**2**	**6**	**4**	**14**
White	**26**	**27**	**22**	**24**	**99**
More than one race	**0**	**1**	**0**	**0**	**1**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Multiple Sleep Latency Test (MSLT) at Endpoint (Last Postbaseline Observation Up to Week 12) [Time Frame: Baseline, last postbaseline observation up to Week 12]

Measure Type	Primary
Measure Title	Change From Baseline in Multiple Sleep Latency Test (MSLT) at Endpoint (Last Postbaseline Observation Up to Week 12)
Measure Description	The MSLT is an objective assessment of sleepiness that measures the likelihood of falling asleep. Four 20-minute (maximum) MSLT naps were performed at 0900, 1100, 1300, and 1500. The participant, dressed in nonconstricting clothes, was instructed to lie quietly and attempt sleep. Each MSLT nap continued until: (a) 3 consecutive 30-second epochs of stage 1 sleep were reached or (b) any single, 30-second epoch of stage 2, 3, 4, or rapid eye movement (REM) sleep was reached. Sleep latency for each nap and average sleep latency for the 4 naps were tabulated. According to clinical protocol for the MSLT, each nap was terminated after 20 minutes if no sleep occurred. If a participant did not fall asleep in 20 minutes, his/her sleep latency for that nap was set to 20 minutes. Sleep latency was measured as the elapsed time from lights-out to the first epoch scored as sleep. With a 30-second scoring epoch, this criterion was reached when sleep occupied at least 16 seconds of any epoch.
Time Frame	Baseline, last postbaseline observation up to Week 12
Safety Issue	No

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.
Full Analysis Set (all participants who received 1 or more doses of study drug with ≥1 postbaseline primary efficacy assessment); n=number of participants with measurements at given time point.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day
Number of Participants Analyzed [units: participants]	**29**	**29**	**28**	**27**
Change From Baseline in Multiple Sleep Latency Test (MSLT) at Endpoint (Last Postbaseline Observation Up to Week 12) [units: minutes] Mean (Standard Deviation)				
Baseline (BL; n=29, 29, 28, 27)	**3.3 (1.79)**	**4.2 (1.69)**	**4.2 (2.05)**	**3.7 (2.04)**
Change from BL at Endpoint (n=27, 29, 26, 21)	**2.4 (4.03)**	**2.6 (4.35)**	**5.0 (4.95)**	**7.2 (6.35)**

Statistical Analysis 1 for Change From Baseline in Multiple Sleep Latency Test (MSLT) at Endpoint (Last Postbaseline Observation Up to Week 12)

Groups [1]	Placebo vs. Armodafinil 50 mg/Day
Method [2]	ANCOVA
P Value [3]	0.8336

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	P-value for “Change from Baseline at Endpoint.”
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The analyses performed were not done in accordance to the study protocol as the study was terminated early and therefore the analyses done were underpowered, no adjustments for multiple comparisons (or step-down analysis rules) were applied.

Statistical Analysis 2 for Change From Baseline in Multiple Sleep Latency Test (MSLT) at Endpoint (Last Postbaseline Observation Up to Week 12)

Groups [1]	Placebo vs. Armodafinil 150 mg/Day
Method [2]	ANCOVA
P Value [3]	0.0514

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	P-value for “Change from Baseline at Endpoint.”
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The analyses performed were not done in accordance to the study protocol as the study was terminated early and therefore the analyses done were underpowered, no adjustments for multiple comparisons (or step-down analysis rules) were applied.

Statistical Analysis 3 for Change From Baseline in Multiple Sleep Latency Test (MSLT) at Endpoint (Last Postbaseline Observation Up to Week 12)

Groups [1]	Placebo vs. Armodafinil 250 mg/Day
Method [2]	ANCOVA

P Value [3]	0.0010

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	P-value for “Change from Baseline at Endpoint.”
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The analyses performed were not done in accordance to the study protocol as the study was terminated early and therefore the analyses done were underpowered, no adjustments for multiple comparisons (or step-down analysis rules) were applied.

2. Primary: Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Endpoint (Last Postbaseline Observation Up to Week 12) [Time Frame: Last postbaseline observation up to Week 12]

Measure Type	Primary
Measure Title	Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Endpoint (Last Postbaseline Observation Up to Week 12)
Measure Description	The CGI-C is the clinician’s rating of disease severity as compared with pretreatment, assessed by the Clinical Global Impression of Severity (CGI-S). Severity of illness, as related to excessive sleepiness, was assessed at baseline by the CGI-S, which consists of 7 categories: normal–shows no sign of illness, borderline ill, mildly (slightly) ill, moderately ill, markedly ill, severely ill, and among the most extremely ill. The clinician assessed the change from baseline in the participant’s condition, as related to excessive sleepiness, in response to treatment. The CGI-C uses the following 7 categories and scoring assignments: very much improved, much improved, minimally improved, no change, minimally worse, much worse, and very much worse. Responders were defined as those participants who were considered much or very much improved on the CGI-C. Those in all other categories of the CGI-C were considered nonresponders.
Time Frame	Last postbaseline observation up to Week 12
Safety Issue	No

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.
Full Analysis Set (all participants who received 1 or more doses of study drug with ≥1 postbaseline primary efficacy assessment).

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**29**	**29**	**28**	**27**
Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Endpoint (Last Postbaseline Observation Up to Week 12) [units: percentage of participants]				

Responders	**38**	**41**	**54**	**48**
Nonresponders	**62**	**59**	**46**	**52**

Statistical Analysis 1 for Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Endpoint (Last Postbaseline Observation Up to Week 12)

Groups [1]	Placebo vs. Armodafinil 50 mg/Day
Method [2]	Pearson's chi-squared
P Value [3]	0.7884

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Endpoint (Last Postbaseline Observation Up to Week 12)

Groups [1]	Placebo vs. Armodafinil 150 mg/Day
Method [2]	Pearson's chi-squared
P Value [3]	0.2359

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Endpoint (Last Postbaseline Observation Up to Week 12)

Groups [1]	Placebo vs. Armodafinil 250 mg/Day
Method [2]	Pearson's chi-squared
P Value [3]	0.4401

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

3. Secondary: Change From Baseline in Mean Sleep Latency From the MSLT at Weeks 4, 8, and 12 [Time Frame: Baseline, Weeks 4, 8, and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean Sleep Latency From the MSLT at Weeks 4, 8, and 12
Measure Description	The MSLT is an objective assessment of sleepiness that measures the likelihood of falling asleep. Four 20-minute (maximum) MSLT naps were performed at 0900, 1100, 1300, and 1500. The participant, dressed in nonconstricting clothes, was instructed to lie quietly and attempt sleep. Each MSLT nap continued until: (a) 3 consecutive 30-second epochs of stage 1 sleep were reached or (b) any single, 30-second epoch of stage 2, 3, 4, or rapid eye movement (REM) sleep was reached. Sleep latency for each nap and average sleep latency for the 4 naps were tabulated. According to clinical protocol for the MSLT, each nap was terminated after 20 minutes if no sleep occurred. Sleep latency was measured as the elapsed time from lights-out to the first epoch scored as sleep. With a 30-second scoring epoch, this criterion was reached when sleep occupied at least 16 seconds of any epoch.
Time Frame	Baseline, Weeks 4, 8, and 12
Safety Issue	No

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.
Full Analysis Set (all participants who received 1 or more doses of study drug with ≥1 postbaseline primary efficacy assessment); n=number of participants with data at given time points.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**29**	**29**	**28**	**27**
Change From Baseline in Mean Sleep Latency From the MSLT at Weeks 4, 8, and 12 [units: minutes] Mean (Standard Deviation)				
Baseline (BL; n=29, 29, 28, 27)	**3.3 (1.79)**	**4.2 (1.69)**	**4.2 (2.05)**	**3.7 (2.04)**
Change from BL at Week 4 (n=26, 29, 26, 20)	**3.2 (4.93)**	**2.7 (5.21)**	**4.0 (5.43)**	**7.0 (4.80)**
Change from BL at Week 8 (n=24, 27, 24, 17)	**2.1 (4.73)**	**2.5 (4.88)**	**4.2 (5.94)**	**4.2 (5.47)**
Change from BL at Week 12 (n=22, 26, 22, 15)	**1.8 (3.87)**	**2.7 (4.53)**	**4.6 (4.39)**	**7.4 (6.38)**

No statistical analysis provided for Change From Baseline in Mean Sleep Latency From the MSLT at Weeks 4, 8, and 12

4. Secondary: Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Weeks 2, 4, 8, and 12 [Time Frame: Weeks 2, 4, 8, and 12]

Measure Type	Secondary
Measure Title	Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Weeks 2, 4, 8, and 12
Measure Description	The CGI-C is the clinician's rating of disease severity as compared with pretreatment, assessed by the Clinical Global Impression of Severity (CGI-S). Severity of illness, as related to excessive sleepiness, was assessed at baseline by the CGI-S, which consists of 7 categories: normal–shows no sign of illness, borderline ill, mildly (slightly) ill, moderately ill, markedly ill, severely ill, and among the most extremely ill. The clinician assessed the change from baseline in the participant's condition, as related to excessive sleepiness, in response to treatment. The CGI-C uses the following 7 categories and scoring assignments: very much improved, much improved, minimally improved, no change, minimally worse, much worse, and very much worse. Responders were defined as those participants who were considered much or very much improved on the CGI-C. Those in all other categories of the CGI-C were considered nonresponders.
Time Frame	Weeks 2, 4, 8, and 12
Safety Issue	No

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.
Full Analysis Set (all participants who received 1 or more doses of study drug with ≥1 postbaseline primary efficacy assessment); n=number of participants with a nonmissing value at given time point.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**29**	**29**	**28**	**27**
Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Weeks 2, 4, 8, and 12 [units: percentage of participants]				
Week 2 Responders (n=28, 29, 27, 23)	**14**	**21**	**37**	**39**
Week 2 Nonresponders (n=28, 29, 27, 23)	**86**	**79**	**63**	**61**
Week 4 Responders (n=27, 29, 26, 20)	**22**	**24**	**50**	**50**
Week 4 Nonresponders (n=27, 29, 26, 20)	**78**	**76**	**50**	**50**
Week 8 Responders (n=23, 27, 24, 18)	**35**	**48**	**54**	**56**
Week 8 Nonresponders (n=23, 27, 24, 18)	**65**	**52**	**46**	**44**
Week 12 Responders (n=23, 26, 22, 16)	**35**	**42**	**55**	**56**
Week 12 Nonresponders (n=23, 26, 22, 16)	**65**	**58**	**45**	**44**

No statistical analysis provided for Percentage of Responders and Nonresponders According to Clinical Global Impression of Change (CGI-C) Ratings at Weeks 2, 4, 8, and 12

5. Secondary: Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Total Score At Weeks 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to Week 12) [Time Frame: Weeks 4, 8, 12 and Endpoint (last postbaseline observation up to Week 12)]

Measure Type	Secondary
Measure Title	Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Total Score At Weeks 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to Week 12)
Measure Description	The TBI-WIS is a validated participant-rated instrument for assessing a participant's functional ability after TBI and the functional demands of their job. The assessment consists of 36 questions to which the participant responded with a "true" or "not true" answer. To score the questionnaire, the number of "true" responses is counted: if < 2, the risk is low; 2 to 23, the risk is medium; and >23, the risk is high, for work instability. Score range is 0 (lowest risk for work instability) to 36 (highest risk for work instability).
Time Frame	Weeks 4, 8, 12 and Endpoint (last postbaseline observation up to Week 12)
Safety Issue	No

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.
Participants in the Full Analysis Set (participants who received 1 or more doses of study drug with ≥1 postbaseline primary efficacy assessment) with a baseline TBI-WIS measurement; n=number of participants with values at given time points.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**24**	**24**	**19**	**21**
Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Total Score At Weeks 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to Week 12) [units: units on a scale] Mean (Standard Deviation)				
Baseline (BL; n=24, 24, 19, 21)	**8.5 (6.75)**	**9.3 (8.80)**	**8.7 (7.55)**	**11.6 (10.71)**
Change from BL at Week 4 (n=23, 23, 18, 15)	**-2.5 (4.71)**	**-2.5 (3.72)**	**-0.5 (3.71)**	**-2.8 (3.88)**
Change from BL at Week 8 (n=19, 22, 17, 13)	**-1.4 (5.52)**	**-3.5 (4.94)**	**-2.4 (5.26)**	**-4.7 (8.89)**
Change from BL at Week 12 (n=19, 21, 17, 12)	**-0.9 (6.27)**	**-3.9 (4.74)**	**-2.5 (4.32)**	**-5.0 (6.90)**
Change from BL at Endpoint (n=24, 24, 19, 19)	**-2.3 (6.44)**	**-3.4 (4.60)**	**-2.5 (4.07)**	**-2.5 (7.12)**

No statistical analysis provided for Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Total Score At Weeks 4, 8,

12 and Endpoint (Last Postbaseline Observation Up to Week 12)

6. Secondary: Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 12 and Endpoint (Last Postbaseline Observation Up to Week 12) [Time Frame: Baseline, Week 12, Endpoint (last postbaseline observation, up to Week 12)]

Measure Type	Secondary
Measure Title	Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 12 and Endpoint (Last Postbaseline Observation Up to Week 12)
Measure Description	The patient's evaluation of excessive daytime sleepiness was measured by the ESS. The ESS score is based on responses to questions referring to 8 everyday situations (eg, sitting and reading, talking to someone, being stopped in traffic) and reflects a patient's propensity to fall asleep in those situations. The ESS score is derived from the sum of the values from questions corresponding to the 8 situations. Scores for the ESS range from 0 to 24, with a higher score indicating a greater daytime sleepiness. This test was self-administered.
Time Frame	Baseline, Week 12, Endpoint (last postbaseline observation, up to Week 12)
Safety Issue	No

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.
Full Analysis Set (all participants who received 1 or more doses of study drug with ≥1 postbaseline primary efficacy assessment); n=number of participants with data at given time point.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**29**	**29**	**28**	**27**
Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 12 and Endpoint (Last Postbaseline Observation Up to Week 12) [units: units on a scale] Mean (Standard Deviation)				
Baseline (BL; n=29, 29, 28, 27)	**14.8 (2.83)**	**14.3 (2.61)**	**15.1 (2.54)**	**16.1 (3.82)**
Change from BL at Week 12 (n=23, 26, 22, 16)	**-5.0 (6.12)**	**-4.6 (5.30)**	**-6.5 (4.40)**	**-9.2 (4.90)**
Change from BL at Endpoint (n=27, 28, 26, 23)	**-5.1 (5.93)**	**-4.5 (5.15)**	**-6.1 (4.52)**	**-7.0 (5.61)**

No statistical analysis provided for Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 12 and Endpoint (Last Postbaseline Observation Up to Week 12)

7. Secondary: Percentage of Participants Answering "No" to All Questions on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to Week 12) [Time Frame: Weeks 4, 8, 12 and Endpoint (last postbaseline observation up to Week 12)]

Measure Type	Secondary
Measure Title	Percentage of Participants Answering "No" to All Questions on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to Week 12)
Measure Description	The C-SSRS captures occurrence, severity, and frequency of suicide-related thoughts and behaviors since last visit (SLV). The number of participants answering 'no' to all 9 yes/no questions about suicidal behaviors, ideations, and acts are presented. Questions included the presence of the following: a wish to be dead; nonspecific active suicidal thoughts; actual suicide attempt; non-suicidal self-injurious behavior; interrupted attempt; aborted attempt; suicidal behavior; preparatory suicidal acts or behavior; and completed suicide.
Time Frame	Weeks 4, 8, 12 and Endpoint (last postbaseline observation up to Week 12)
Safety Issue	Yes

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.
Safety analysis set (all participants who received 1 or more doses of study drug); n=all participants with a nonmissing value at given time point.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**29**	**30**	**29**	**29**
Percentage of Participants Answering "No" to All Questions on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to Week 12) [units: percentage of participants]				
Week 2 (n=14, 14, 13, 12)	**100**	**100**	**100**	**100**
Week 4 (n=13, 16, 15, 11)	**100**	**100**	**100**	**100**
Week 8 (n=13, 15, 13, 10)	**100**	**100**	**100**	**100**
Week 12 (n=14, 15, 13, 9)	**100**	**100**	**100**	**100**
Endpoint (n=19, 18, 16, 15)	**100**	**100**	**100**	**100**

No statistical analysis provided for Percentage of Participants Answering "No" to All Questions on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to Week 12)

8. Secondary: Change From Baseline in the Total Score From the Self-Reported Hamilton Depression Rating Scale, 6 Item Version (S-HAM-D6) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks) [Time Frame: Baseline, Weeks 2, 4, 8, 12, and Endpoint (last postbaseline observation up to 12 weeks)]

Measure Type	Secondary
Measure Title	Change From Baseline in the Total Score From the Self-Reported Hamilton Depression Rating Scale, 6 Item Version (S-HAM-D6) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks)
Measure Description	The self-reported S-HAM-D6 is a validated scale developed from the core depressive items of the 17 Item Hamilton Depression Inventory (HAM-D17). The HAM-D6 (Items 1, 2, 7, 8, 10, 13 from the 17-item HAMD) evaluates "core" symptoms of Major Depressive Disorder (MDD). The assessment consists of 6 items representing depressed mood, guilt, work and activities, retardation, psychic anxiety, and general somatic symptoms. Each item is evaluated and scored using either a 5-point scale (e.g. absent, mild, moderate, severe, very severe) or a 3-point scale (e.g. absent, mild, marked). Total scores range from 0 (normal) to 22 (severe). Scores greater than 12 indicate moderate to severe depression and scores less than 12 indicate mild depression.
Time Frame	Baseline, Weeks 2, 4, 8, 12, and Endpoint (last postbaseline observation up to 12 weeks)
Safety Issue	Yes

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.
Participants in the Safety Analysis Set (participants who received 1 or more doses of study drug) with a baseline S-HAM-D6 measurement; n=number of participants with nonmissing data at given time point.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**13**	**13**	**11**	**13**
Change From Baseline in the Total Score From the Self-Reported Hamilton Depression Rating Scale, 6 Item Version (S-HAM-D6) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks) **[units: units on a scale]** **Mean (Standard Deviation)**				
Baseline (BL; n=13, 13, 11, 13)	**1.3 (1.49)**	**1.8 (1.07)**	**1.2 (1.72)**	**1.5 (1.33)**
Change from BL at Week 2 (n=13, 13, 11, 11)	**-0.7 (1.38)**	**-0.5 (2.63)**	**0.3 (1.49)**	**0.4 (1.29)**
Change from BL at Week 4 (n=12, 12, 11, 10)	**-0.5 (1.62)**	**0.9 (2.68)**	**-0.2 (1.47)**	**0.2 (2.97)**
Change from BL at Week 8 (n=10, 11, 10, 9)	**0.1 (1.60)**	**1.1 (4.68)**	**-0.2 (1.40)**	**1.6 (3.05)**
Change from BL at Week 12 (n=9, 10, 9, 8)	**0.9 (2.80)**	**0.2 (2.74)**	**1.0 (2.65)**	**-0.1 (2.17)**
Change from BL at Endpoint (n=13, 13, 11, 13)	**0.5 (2.54)**	**-0.1 (2.43)**	**0.6 (2.54)**	**0.9 (4.41)**

No statistical analysis provided for Change From Baseline in the Total Score From the Self-Reported Hamilton Depression Rating Scale, 6 Item Version (S-HAM-D6) at Weeks 2, 4, 8, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks)

9. Secondary: Change From Baseline in the Total Sleep Time As Assessed by Nocturnal Polysomnography (NPSG) at Weeks 2, 4, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks) [Time Frame: Baseline, Weeks 2, 4, 12, and Endpoint (last postbaseline observation up to 12 weeks)]

Measure Type	Secondary
Measure Title	Change From Baseline in the Total Sleep Time As Assessed by Nocturnal Polysomnography (NPSG) at Weeks 2, 4, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks)
Measure Description	NPSG continuously records normal and abnormal physiological activity during an entire night. It documents the adequacy of sleep, including the frequency, duration, and total amounts of stage 1-2, stage 3-4 (slow wave sleep), and rapid eye movement (REM) sleep.
Time Frame	Baseline, Weeks 2, 4, 12, and Endpoint (last postbaseline observation up to 12 weeks)
Safety Issue	Yes

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.
Safety Analysis Set (all participants who received 1 or more doses of study drug); n=number of participants with data at given time point.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day
Number of Participants Analyzed [units: participants]	**29**	**30**	**29**	**29**
Change From Baseline in the Total Sleep Time As Assessed by Nocturnal Polysomnography (NPSG) at Weeks 2, 4, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks) [units: minutes] Mean (Standard Deviation)				
Baseline (BL; n=29, 30, 29, 29)	**442.3 (19.60)**	**442.4 (18.38)**	**442.0 (19.07)**	**442.8 (19.16)**
Change from BL at Week 2 (n=28, 29, 27, 24)	**-4.4 (29.62)**	**5.8 (27.14)**	**-3.9 (38.10)**	**-8.8 (41.85)**
Change from BL at Week 4 (n=26, 28, 26, 21)	**-16.9 (78.81)**	**2.9 (34.50)**	**4.0 (41.32)**	**-21.6 (51.18)**
Change from BL at Week 12 (n=22, 26, 22, 15)	**-0.5 (24.39)**	**8.3 (20.46)**	**-18.3 (62.26)**	**-33.1 (55.65)**
Change from BL at Endpoint (n=29, 30, 27, 26)	**-10.1 (35.75)**	**6.6 (21.37)**	**-19.7 (60.53)**	**-21.2 (46.77)**

No statistical analysis provided for Change From Baseline in the Total Sleep Time As Assessed by Nocturnal Polysomnography (NPSG) at Weeks 2, 4, 12 and Endpoint (Last Postbaseline Observation Up to 12 Weeks)

10. Secondary: Plasma Concentrations of Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) at Weeks 4, 8, and 12 (or Last Postbaseline Observation Up to Week 12) [Time Frame: Weeks 4, 8, and 12 (or last postbaseline observation, up to Week 12)]

Measure Type	Secondary
Measure Title	Plasma Concentrations of Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) at Weeks 4, 8, and 12 (or Last Postbaseline Observation Up to Week 12)
Measure Description	To evaluate the impact of treatment with armodafinil on the pharmacokinetics of selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs) (as appropriate), plasma concentrations at weeks 4, 8, and 12 (or last postbaseline observation) were to be assessed.
Time Frame	Weeks 4, 8, and 12 (or last postbaseline observation, up to Week 12)
Safety Issue	No

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.
Due to the limited samples available for measurement of concentrations of antidepressants in the study, the plasma concentrations of antidepressants were not measured. The planned pharmacokinetic evaluation of the impact of armodafinil treatment on the pharmacokinetics of selective antidepressants was not conducted.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Plasma Concentrations of Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) at Weeks 4, 8, and 12 (or Last Postbaseline Observation Up to Week 12)				

No statistical analysis provided for Plasma Concentrations of Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) at Weeks 4, 8, and 12 (or Last Postbaseline Observation Up to Week 12)

11. Secondary: Concomitant Medication Usage In ≥5% of Participants Throughout the Study [Time Frame: Screening through Week 12]

Measure Type	Secondary
Measure Title	Concomitant Medication Usage In ≥5% of Participants Throughout the Study
Measure Description	Therapeutic classification of concomitant medications used by ≥5% of participants throughout the study. Participants are counted only once in each therapeutic class category. Medications were included in the table if the proportion of participants in the combined armodafinil treatment group was ≥5%.
Time Frame	Screening through Week 12
Safety Issue	Yes

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.
All randomized participants

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**29**	**30**	**29**	**29**
Concomitant Medication Usage In ≥5% of Participants Throughout the Study [units: participants]				
Analgesics	**4**	**4**	**7**	**6**
Antibacterials	**2**	**2**	**1**	**2**
Antihistamines for systemic use	**1**	**2**	**4**	**2**
Anti-inflammatory and antirheumatic products	**8**	**9**	**5**	**8**
Drugs for acid-related disorders	**0**	**2**	**2**	**2**
Lipid-modifying agents	**2**	**8**	**2**	**2**
Nasal preparations	**2**	**3**	**1**	**2**
Sex hormones and modulators of the genital system	**3**	**4**	**3**	**3**
Unspecified herbal	**1**	**3**	**1**	**1**
Vitamins/nutritional supplement	**5**	**7**	**4**	**7**

No statistical analysis provided for Concomitant Medication Usage In ≥5% of Participants Throughout the Study

12. Secondary: Number of Participants With Adverse Events (AEs), Serious AEs (SAEs), Deaths, and Withdrawals Due to AEs [Time Frame: Screening through Week 12]

Measure Type	Secondary
Measure Title	Number of Participants With Adverse Events (AEs), Serious AEs (SAEs), Deaths, and Withdrawals Due to AEs
Measure Description	AE=any untoward medical occurrence in a patient that develops or worsens in severity during the conduct of the clinical study of a pharmaceutical product and does not necessarily have a causal relationship to the study drug. SAE=any AE that resulted in any of the following: death; a life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; a congenital anomaly or birth defect; an important medical event that required medical intervention to prevent 1 of the outcomes listed in this definition. Treatment-related AEs=definite, probable, possible, or missing relationship. Protocol-defined AEs=treatment-emergent adverse events associated with skin rash, hypersensitivity reaction, emergent suicidal ideation or suicide attempt, depression, psychosis (including hypomanic or manic episode), and seizure or suspected seizure were considered to be of potential clinical importance.

Time Frame	Screening through Week 12
Safety Issue	Yes

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.
Safety Analysis Set (all participants who received 1 or more doses of study drug).

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day
Number of Participants Analyzed [units: participants]	**29**	**30**	**29**	**29**
Number of Participants With Adverse Events (AEs), Serious AEs (SAEs), Deaths, and Withdrawals Due to AEs [units: participants]				
Any adverse event	**14**	**15**	**16**	**16**
Severe adverse events	**0**	**0**	**0**	**0**
Treatment-related adverse events	**8**	**9**	**14**	**15**
Deaths	**0**	**0**	**0**	**0**
Other serious adverse events	**0**	**0**	**0**	**0**
Withdrawn from study due to adverse events	**0**	**2**	**1**	**5**
Protocol-defined adverse event	**0**	**1**	**0**	**3**

No statistical analysis provided for Number of Participants With Adverse Events (AEs), Serious AEs (SAEs), Deaths, and Withdrawals Due to AEs

13. Secondary: Number of Participants With Clinically Significant Abnormal Postbaseline Serum Chemistry Values [Time Frame: Baseline, last postbaseline observation up to Week 12]

Measure Type	Secondary
Measure Title	Number of Participants With Clinically Significant Abnormal Postbaseline Serum Chemistry Values
Measure Description	Normal ranges for serum chemistry values: blood urea nitrogen (BUN), 1.43 - 8.57 mmol/L; uric acid, 124.91 - 493.68 µmol/L; aspartate aminotransferase (AST), 11 - 36 U/L; gamma-glutamyl transpeptidase (GGT), 10 - 61 U/L; total bilirubin, 3.42 - 20.52 µmol/L.
Time Frame	Baseline, last postbaseline observation up to Week 12
Safety Issue	Yes

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.
Participants in the Safety Analysis Set with a baseline and postbaseline measurement.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day
Number of Participants Analyzed [units: participants]	**29**	**30**	**28**	**28**
Number of Participants With Clinically Significant Abnormal Postbaseline Serum Chemistry Values [units: participants]				
BUN >=10.71 mmol/L	**1**	**0**	**0**	**0**
Uric acid >=625 (men) or >=506 (women) µmol/L	**0**	**1**	**0**	**0**
AST >=3 x upper limit of normal	**0**	**0**	**1**	**0**
GGT >=3 x upper limit of normal	**0**	**1**	**0**	**0**
Total bilirubin >=34.2 µmol/L	**0**	**1**	**1**	**0**

No statistical analysis provided for Number of Participants With Clinically Significant Abnormal Postbaseline Serum Chemistry Values

14. Secondary: Number of Participants With Clinically Significant Abnormal Postbaseline Hematology Values [Time Frame: Baseline, last postbaseline observation up to Week 12]

Measure Type	Secondary
Measure Title	Number of Participants With Clinically Significant Abnormal Postbaseline Hematology Values
Measure Description	Normal ranges for hematology values: white blood cell (WBC) count, 3.8 - 10.7 x 10^9/L; absolute neutrophil count (ANC), 1.96 - 7.23 x 10^9/L. Participants may have had more than one clinically significant abnormal value.
Time Frame	Baseline, last postbaseline observation up to Week 12
Safety Issue	Yes

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.
Participants in the Safety Analysis Set with a baseline and postbaseline measurement.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)

Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day
Number of Participants Analyzed [units: participants]	**29**	**30**	**28**	**28**
Number of Participants With Clinically Significant Abnormal Postbaseline Hematology Values [units: participants]				
WBC <=3.0 x 10^9/L	**1**	**1**	**1**	**0**
ANC <=1.0 x 10^9/L	**1**	**0**	**0**	**0**

No statistical analysis provided for Number of Participants With Clinically Significant Abnormal Postbaseline Hematology Values

15. Secondary: Number of Participants With Clinically Significant Abnormal Postbaseline Urinalysis Values [Time Frame: Baseline, last postbaseline observation up to Week 12]

Measure Type	Secondary
Measure Title	Number of Participants With Clinically Significant Abnormal Postbaseline Urinalysis Values
Measure Description	Participants with at least one clinically significant postbaseline urinalysis abnormality, specifically presented is blood (hemoglobin) in urine >=2 units increase from baseline.
Time Frame	Baseline, last postbaseline observation up to Week 12
Safety Issue	Yes

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.
Participants in the Safety Analysis Set with a baseline and postbaseline measurement.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day
Number of Participants Analyzed [units: participants]	**29**	**30**	**28**	**28**
Number of Participants With Clinically Significant Abnormal Postbaseline Urinalysis Values [units: participants]	**2**	**1**	**1**	**1**

No statistical analysis provided for Number of Participants With Clinically Significant Abnormal Postbaseline Urinalysis Values

16. Secondary: Number of Participants With Clinically Significant Abnormal Vital Sign Values [Time Frame: Baseline, last postbaseline observation up to Week 12]

Measure Type	Secondary
Measure Title	Number of Participants With Clinically Significant Abnormal Vital Sign Values
Measure Description	Criteria for clinically significant abnormal vital signs values: heart rate, ≤50 beats per minute (bpm) and decrease from baseline of ≥15 bpm; sitting systolic blood pressure, ≤90 mm Hg and decrease from baseline of ≥20 mm Hg; sitting diastolic blood pressure, ≤50 mm Hg and decrease from baseline of ≥15 mm Hg.
Time Frame	Baseline, last postbaseline observation up to Week 12
Safety Issue	Yes

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.
Participants in the Safety Analysis Set with a baseline and postbaseline measurement.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**29**	**30**	**28**	**29**
Number of Participants With Clinically Significant Abnormal Vital Sign Values [units: participants]				
Heart Rate	**0**	**1**	**1**	**0**
Sitting Systolic Blood Pressure	**0**	**1**	**0**	**0**
Sitting Diastolic Blood Pressure	**0**	**1**	**0**	**0**

No statistical analysis provided for Number of Participants With Clinically Significant Abnormal Vital Sign Values

17. Secondary: Number of Participants With Notable Blood Pressure Values Per World Health Organization Criteria [Time Frame: Baseline, last postbaseline observation up to Week 12]

Measure Type	Secondary
Measure Title	Number of Participants With Notable Blood Pressure Values Per World Health Organization Criteria
Measure Description	Criteria for World Health Organization (WHO) notable blood pressure (BP) values: systolic blood pressure, ≥140 mm Hg plus increase of ≥10% from baseline; diastolic blood pressure, ≥90 mm Hg plus increase of ≥10% from baseline.
Time Frame	Baseline, last postbaseline observation up to Week 12

Safety Issue	Yes

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.
Participants in the Safety Analysis Set with a baseline and postbaseline measurement.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Number of Participants Analyzed [units: participants]	**29**	**30**	**28**	**29**
Number of Participants With Notable Blood Pressure Values Per World Health Organization Criteria [units: participants]				
Sitting Systolic Blood Pressure	**0**	**1**	**1**	**2**
Sitting Diastolic Blood Pressure	**0**	**2**	**0**	**2**

No statistical analysis provided for Number of Participants With Notable Blood Pressure Values Per World Health Organization Criteria

18. Secondary: Electrocardiogram (ECG) Findings Shifts From Baseline to Overall [Time Frame: Baseline through Endpoint (last postbaseline observation, up to Week 12)]

Measure Type	Secondary
Measure Title	Electrocardiogram (ECG) Findings Shifts From Baseline to Overall
Measure Description	Number of participants with shifts from normal/abnormal 12-lead ECG findings at baseline (BL) to (→) normal/abnormal findings overall are presented. For overall, the worst postbaseline finding (the abnormal finding if there are both normal and abnormal findings) for the participant between baseline and endpoint (defined as last postbaseline observation, up to Week 12) is summarized. Shifts (normal and abnormal) from baseline to overall are summarized using participant counts. Any ECG finding that was judged by the investigator as a clinically meaningful change (worsening) compared to baseline was recorded as an adverse event.
Time Frame	Baseline through Endpoint (last postbaseline observation, up to Week 12)
Safety Issue	Yes

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.
Participants in the Safety Analysis Set with a baseline and postbaseline measurement are summarized.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)

Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day
Number of Participants Analyzed [units: participants]	**28**	**27**	**27**	**27**
Electrocardiogram (ECG) Findings Shifts From Baseline to Overall [units: participants]				
Normal at BL → Normal Overall	**15**	**16**	**14**	**15**
Normal at BL → Abnormal Overall	**1**	**2**	**4**	**1**
Abnormal at BL → Normal Overall	**3**	**3**	**7**	**3**
Abnormal at BL → Abnormal Overall	**9**	**6**	**2**	**8**

No statistical analysis provided for Electrocardiogram (ECG) Findings Shifts From Baseline to Overall

19. Secondary: Physical Examination Findings Shifts From Baseline to Endpoint (Last Postbaseline Observation, up to Week 12) [Time Frame: Baseline through Endpoint (last postbaseline observation, up to Week 12)]

Measure Type	Secondary
Measure Title	Physical Examination Findings Shifts From Baseline to Endpoint (Last Postbaseline Observation, up to Week 12)
Measure Description	Number of participants with shifts from normal/abnormal physical examination findings at baseline (BL) to (→) normal/abnormal findings at endpoint (EP, defined as last postbaseline observation, up to Week 12). Shifts (normal and abnormal) from baseline to endpoint are summarized using participant counts for each physical examination category. A newly diagnosed finding was defined as being normal or missing at baseline and abnormal at least once during the study. Any physical examination finding that was judged by the investigator as a clinically significant change (worsening) compared to a baseline value was considered an adverse event. HEENT=head, eyes, ears, nose, throat.
Time Frame	Baseline through Endpoint (last postbaseline observation, up to Week 12)
Safety Issue	Yes

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.
For each category, only participants in the Safety Analysis Set with a baseline and postbaseline measurement are summarized.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Measured Values

	Placebo	Armodafinil 50 mg/Day	Armodafinil 150 mg/Day	Armodafinil 250 mg/Day
Number of Participants Analyzed [units: participants]	29	30	29	29
Physical Examination Findings Shifts From Baseline to Endpoint (Last Postbaseline Observation, up to Week 12) [units: participants]				
General Appearance: Normal at BL → Normal at EP	26	27	26	27
General Appearance: Normal at BL → Abnormal at EP	0	0	0	0
General Appearance: Abnormal at BL → Normal at EP	0	2	1	0
General Appearance:Abnormal at BL → Abnormal at EP	2	0	0	0
HEENT: Normal at BL→ Normal at EP	26	29	24	26
HEENT: Normal at BL→ Abnormal at EP	1	0	1	0
HEENT: Abnormal at BL→ Normal at BL	0	0	1	0
HEENT: Abnormal at BL→ Abnormal at EP	1	0	1	1
Chest/Lungs: Normal at BL→ Normal at EP	28	29	27	27
Chest/Lungs: Normal at BL→ Abnormal at EP	0	0	0	0
Chest/Lungs: Abnormal at BL→ Normal at EP	0	0	0	0
Chest/Lungs: Abnormal at BL→ Abnormal at EP	0	0	0	0
Heart: Normal at BL → Normal at EP	26	29	27	26
Heart: Normal at BL → Abnormal at EP	0	0	0	1
Heart: Abnormal at BL → Normal at EP	2	0	0	0
Heart: Abnormal at BL → Abnormal at EP	0	0	0	0
Abdomen: Normal at BL → Normal at EP	27	27	26	26
Abdomen: Normal at BL → Abnormal at EP	0	0	0	0
Abdomen: Abnormal at BL → Normal at EP	0	2	1	0
Abdomen: Abnormal at BL → Abnormal at EP	1	0	0	0
Musculoskeletal: Normal at BL → Normal at EP	27	29	25	27
Musculoskeletal: Normal at BL → Abnormal at EP	0	0	0	0
Musculoskeletal: Abnormal at BL → Normal at EP	1	0	1	0
Musculoskeletal: Abnormal at BL → Abnormal at EP	0	0	1	0
Skin: Normal at BL → Normal at EP	25	24	24	24
Skin: Normal at BL → Abnormal at EP	0	1	0	1
Skin: Abnormal at BL → Normal at EP	0	1	0	1
Skin: Abnormal at BL → Abnormal at EP	3	3	3	1
Lymph Nodes: Normal at BL → Normal at EP	25	26	24	27
Lymph Nodes: Normal at BL → Abnormal at EP	0	1	0	0
Lymph Nodes: Abnormal at BL → Normal at EP	0	0	1	0
Lymph Nodes: Abnormal at BL → Abnormal at EP	0	0	0	0
Neurological: Normal at BL → Normal at EP	26	28	27	27
Neurological: Normal at BL → Abnormal at EP	0	0	0	0
Neurological: Abnormal at BL → Normal at EP	0	1	0	0

Neurological: Abnormal at BL → Abnormal at EP	**2**	**0**	**0**	**0**

No statistical analysis provided for Physical Examination Findings Shifts From Baseline to Endpoint (Last Postbaseline Observation, up to Week 12)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Screening through Week 12
Additional Description	No text entered.

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Serious Adverse Events

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Total, serious adverse events				
# participants affected / at risk	**0/29 (0.00%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Screening through Week 12
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Placebo	Oral placebo tablets, once daily (QD)
Armodafinil 50 mg/Day	Oral armodafinil 50 mg tablets, once daily (QD)
Armodafinil 150 mg/Day	Oral armodafinil 150 mg tablets, once daily (QD)
Armodafinil 250 mg/Day	Oral armodafinil 250 mg tablets, once daily (QD)

Other Adverse Events

	Placebo	**Armodafinil 50 mg/Day**	**Armodafinil 150 mg/Day**	**Armodafinil 250 mg/Day**
Total, other (not including serious) adverse events				

# participants affected / at risk	14/29 (48.28%)	15/30 (50.00%)	16/29 (55.17%)	16/29 (55.17%)
Blood and lymphatic system disorders				
Lymphadenopathy † 1				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	0/29 (0.00%)	0/29 (0.00%)
Cardiac disorders				
Palpitations † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Eye disorders				
Vision blurred † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Conjunctival haemorrhage † 1				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	0/29 (0.00%)	0/29 (0.00%)
Gastrointestinal disorders				
Nausea † 1				
# participants affected / at risk	0/29 (0.00%)	3/30 (10.00%)	3/29 (10.34%)	3/29 (10.34%)
Diarrhoea † 1				
# participants affected / at risk	1/29 (3.45%)	1/30 (3.33%)	0/29 (0.00%)	3/29 (10.34%)
Dry mouth † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	2/29 (6.90%)
Abdominal discomfort † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Abdominal pain † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Gastroesophageal reflux disease † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Toothache † 1				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	0/29 (0.00%)	0/29 (0.00%)
General disorders				
Feeling jittery † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	2/29 (6.90%)
Fatigue † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Feeling abnormal † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Irritability † 1				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Pyrexia † 1				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Infections and infestations				
Upper respiratory tract infection † 1				
# participants affected / at risk	1/29 (3.45%)	1/30 (3.33%)	3/29 (10.34%)	0/29 (0.00%)
Sinusitis † 1				
# participants affected / at risk	1/29 (3.45%)	1/30 (3.33%)	0/29 (0.00%)	2/29 (6.90%)

Influenza [†1]				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	0/29 (0.00%)	1/29 (3.45%)
Nasopharyngitis [†1]				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	1/29 (3.45%)	0/29 (0.00%)
Pharyngitis [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Pharyngitis streptococcal [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Rhinitis [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Urinary tract infection [†1]				
# participants affected / at risk	1/29 (3.45%)	1/30 (3.33%)	0/29 (0.00%)	0/29 (0.00%)
Kidney infection [†1]				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	0/29 (0.00%)	0/29 (0.00%)
Pneumonia [†1]				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	0/29 (0.00%)	0/29 (0.00%)
Viral infection [†1]				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	0/29 (0.00%)	0/29 (0.00%)
Injury, poisoning and procedural complications				
Arthropod sting [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Contusion [†1]				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	0/29 (0.00%)	0/29 (0.00%)
Investigations				
Blood creatine phosphokinase increased [†1]				
# participants affected / at risk	1/29 (3.45%)	1/30 (3.33%)	0/29 (0.00%)	1/29 (3.45%)
Heart rate increased [†1]				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	0/29 (0.00%)	1/29 (3.45%)
Alanine aminotransferase increased [†1]				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	0/29 (0.00%)	0/29 (0.00%)
Blood alkaline phosphatase increased [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Blood bicarbonate decreased [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Blood potassium increased [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Blood pressure increased [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Blood sodium increased [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Platelet count decreased [†1]				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	0/29 (0.00%)	0/29 (0.00%)
Weight decreased [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)

Weight increased [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Blood creatinine increased [†1]				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	0/29 (0.00%)	0/29 (0.00%)
Electrocardiogram T wave abnormal [†1]				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	0/29 (0.00%)	0/29 (0.00%)
Glucose urine present [†1]				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	0/29 (0.00%)	0/29 (0.00%)
Metabolism and nutrition disorders				
Decreased appetite [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	1/29 (3.45%)
Hyperglycaemia [†1]				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	0/29 (0.00%)	0/29 (0.00%)
Musculoskeletal and connective tissue disorders				
Arthralgia [†1]				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	0/29 (0.00%)	0/29 (0.00%)
Flank pain [†1]				
# participants affected / at risk	0/29 (0.00%)	1/30 (3.33%)	0/29 (0.00%)	0/29 (0.00%)
Musculoskeletal pain [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Back pain [†1]				
# participants affected / at risk	1/29 (3.45%)	0/30 (0.00%)	0/29 (0.00%)	0/29 (0.00%)
Nervous system disorders				
Headache [†1]				
# participants affected / at risk	2/29 (6.90%)	5/30 (16.67%)	5/29 (17.24%)	5/29 (17.24%)
Dizziness [†1]				
# participants affected / at risk	0/29 (0.00%)	2/30 (6.67%)	1/29 (3.45%)	2/29 (6.90%)
Memory impairment [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Sinus headache [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	0/29 (0.00%)	1/29 (3.45%)
Somnolence [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Pregnancy, puerperium and perinatal conditions				
Unintended pregnancy [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	0/29 (0.00%)
Psychiatric disorders				
Anxiety [†1]				
# participants affected / at risk	0/29 (0.00%)	4/30 (13.33%)	0/29 (0.00%)	3/29 (10.34%)
Insomnia [†1]				
# participants affected / at risk	1/29 (3.45%)	1/30 (3.33%)	3/29 (10.34%)	1/29 (3.45%)
Bruxism [†1]				
# participants affected / at risk	0/29 (0.00%)	0/30 (0.00%)	1/29 (3.45%)	1/29 (3.45%)

Depression † 1				
# participants affected / at risk	**0/29 (0.00%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**2/29 (6.90%)**
Initial insomnia † 1				
# participants affected / at risk	**0/29 (0.00%)**	**1/30 (3.33%)**	**1/29 (3.45%)**	**0/29 (0.00%)**
Logorrhoea † 1				
# participants affected / at risk	**0/29 (0.00%)**	**0/30 (0.00%)**	**1/29 (3.45%)**	**0/29 (0.00%)**
Middle insomnia † 1				
# participants affected / at risk	**0/29 (0.00%)**	**1/30 (3.33%)**	**0/29 (0.00%)**	**0/29 (0.00%)**
Tachyphrenia † 1				
# participants affected / at risk	**0/29 (0.00%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**1/29 (3.45%)**
Abnormal dreams † 1				
# participants affected / at risk	**1/29 (3.45%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**
Nightmare † 1				
# participants affected / at risk	**1/29 (3.45%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**
Pressure of speech † 1				
# participants affected / at risk	**1/29 (3.45%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**
Renal and urinary disorders				
Haematuria † 1				
# participants affected / at risk	**0/29 (0.00%)**	**1/30 (3.33%)**	**0/29 (0.00%)**	**0/29 (0.00%)**
Respiratory, thoracic and mediastinal disorders				
Cough † 1				
# participants affected / at risk	**0/29 (0.00%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**1/29 (3.45%)**
Dyspnoea † 1				
# participants affected / at risk	**0/29 (0.00%)**	**0/30 (0.00%)**	**1/29 (3.45%)**	**0/29 (0.00%)**
Oropharyngeal pain † 1				
# participants affected / at risk	**0/29 (0.00%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**1/29 (3.45%)**
Skin and subcutaneous tissue disorders				
Dermatitis contact † 1				
# participants affected / at risk	**0/29 (0.00%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**2/29 (6.90%)**
Eczema † 1				
# participants affected / at risk	**0/29 (0.00%)**	**1/30 (3.33%)**	**0/29 (0.00%)**	**0/29 (0.00%)**
Skin irritation † 1				
# participants affected / at risk	**0/29 (0.00%)**	**0/30 (0.00%)**	**0/29 (0.00%)**	**1/29 (3.45%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

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

The sponsor's decision to terminate the study early resulted in a small number of study participants and related limitations to the interpretation of the study results.

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:** Sponsor has the right 60 days before submission for publication to review/provide comments. If the Sponsor's review shows that potentially patentable subject matter would be disclosed, publication or public disclosure shall be delayed for up to 90 additional days in order for the Sponsor, or Sponsor's designees, to file the necessary patent applications. In multicenter trials, each PI will postpone single center publications until after disclosure or publication of multicenter data.

Results Point of Contact:

Name/Title: Manager, Biopharmaceutics
Organization: Teva Pharmaceuticals USA
phone: 1-866-384-5525
e-mail: clinicaltrialqueries@tevausa.com

No publications provided by Teva Pharmaceutical Industries

Publications automatically indexed to this study:

Menn SJ, Yang R, Lankford A. Armodafinil for the treatment of excessive sleepiness associated with mild or moderate closed traumatic brain injury: a 12-week, randomized, double-blind study followed by a 12-month open-label extension. J Clin Sleep Med. 2014 Nov 15;10(11):1181-91. doi: 10.5664/jcsm.4196.

Responsible Party:	Teva Pharmaceutical Industries (Cephalon)
ClinicalTrials.gov Identifier:	NCT00893789 History of Changes
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