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Trial record **1 of 1** for: C10953/3069/ES/MN

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Study to Evaluate the Safety, Tolerability, and Efficacy 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:
NCT00983437

First received: September 9, 2009
Last updated: August 14, 2013
Last verified: August 2013
History of Changes

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Purpose

The primary objective of this study is to evaluate the safety and tolerability of long-term (12 months) armodafinil treatment in patients with excessive sleepiness associated with mild or moderate closed traumatic brain injury (TBI).

Condition	Intervention	Phase
Traumatic Brain Injury	Drug: Armodafinil	Phase 3

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A 12-Month, Open-Label Study to Evaluate the Safety, Tolerability, and Efficacy of Armodafinil (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:

- Safety and Tolerability: Number of Participants With Adverse Events (AEs), Serious Adverse Events (SAEs), Deaths and Discontinuations Due to AEs [Time Frame: Assessed from Screening through end of treatment; median (full range) of treatment was 98 (5.0 to 326.0) days.] [Designated as safety issue: Yes]

  AE=any untoward medical occurrence 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 to study drug. Protocol-defined AEs=treatment-emergent adverse events associated with skin rash, hypersensitivity reaction, emergent suicidal ideation or suicide attempt, depression, psychosis, and seizure or suspected seizure were considered to be of potential clinical importance. DB=double-blind portion of the study (NCT00893789).

- Safety and Tolerability: Concomitant Medication Usage In Participants Throughout the Study [Time Frame: Assessed from Screening through end of treatment; median (full range) of treatment was 98 (5.0 to 326.0) days.] [Designated as safety issue: Yes]

  Therapeutic classification of concomitant medications used by participants throughout the study. Participants are counted only once in each therapeutic class category.

- Safety and Tolerability: Number of Participants With Clinically Significant Serum Chemistry Test Results [Time Frame: Assessed at Screening, Months 6 and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]
  [Designated as safety issue: Yes]

  Criteria for clinically significant abnormal serum chemistry values: alanine aminotransferase (ALT) ≥3x upper limit of normal (ULN); aspartate aminotransferase (AST) ≥3x ULN; alkaline phosphatase ≥3x ULN; gamma-glutamyl transpeptidase (GGT) ≥3x ULN; lactate dehydrogenase (LDH) ≥3x ULN; blood urea nitrogen (BUN) ≥10.71 mmol/L; creatinine ≥177 µmol/L; uric acid, men ≥625 µmol/L, women ≥506 µmol/L; bilirubin (total) ≥34.2 µmol/L.

- Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Vital Signs Measurements [Time Frame: Baseline, Week 2, Months 1, 2, 3, 6, 9, and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]
  [Designated as safety issue: Yes]

  Criteria for clinically significant abnormal vital signs values: pulse, ≥120 beats per minute (bpm) and increase from baseline of ≥15 bpm or ≤50 bpm and decrease from baseline of ≥15 bpm; systolic blood pressure, ≥180 mm Hg and increase from baseline of ≥20 mm Hg or ≤90 mm Hg and decrease from baseline of ≥20 mm Hg; diastolic blood pressure, ≥105 mm Hg and increase from baseline of ≥15 mm Hg or ≤50 mm Hg and decrease from baseline of ≥15 mm Hg; temperature >38.3º celsius (C) and change from baseline of ≥1.1°C. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

- Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Hematology Test Results [Time Frame: Assessed at Screening, Months 6 and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]
  [Designated as safety issue: Yes]

  Criteria for clinically significant abnormal hematology values: hematocrit, men <0.37 L/L or women <0.32 L/L; hemoglobin, men ≤115 g/L or women ≤95 g/L; white blood cell (WBC) count ≤3x10^9/L or ≥20x10^9/L; eosinophils ≥10%; absolute neutrophil count (ANC) ≤1x10^9/L; platelet count ≤75x10^9/L or ≥700x10^9/L.

- Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Urinalysis Results [Time Frame: Baseline, Months 6 and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.] [Designated as safety issue: Yes]

  Criteria for clinically significant abnormal urinalysis values: blood (hemoglobin) ≥2 unit increase from baseline; glucose ≥2 unit increase from baseline; ketones ≥2 unit increase from baseline; total protein ≥2 unit increase from baseline. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

- Safety and Tolerability: Number of Participants With Notable Blood Pressure Values Per World Health Organization Criteria
  [Time Frame: Baseline, Week 2, Months 1, 2, 3, 6, 9, and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.] [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. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

- Safety and Tolerability: Electrocardiogram (ECG) Findings Shifts From Baseline to Overall [Time Frame: Baseline through Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.] [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. Any ECG finding that was judged by the investigator as a clinically meaningful change (worsening) compared to baseline was recorded as an adverse event. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

- Safety and Tolerability: Physical Examination Findings Shifts From Baseline to Endpoint (Month 12 or Last Postbaseline Observation)
  [Time Frame: Baseline through Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.] [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). 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. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

- Number of Participants Answering "Yes" to Any Question on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation) [Time Frame: Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]
  [Designated as safety issue: Yes]

  The percentage of participants answering 'yes' to any of the 9 yes/no questions about suicidal behaviors, ideations, and acts at given time points are presented. The C-SSRS captures occurrence, severity, and frequency of suicide-related thoughts and behaviors since last visit (SLV). Questions included the presence (yes) or absence (no) 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 Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation) [Time Frame: Baseline, Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]
  [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. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

Secondary Outcome Measures:

- Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Baseline, Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.] [Designated as safety issue: No]

  The participant'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. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

- Change From Baseline in Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Baseline, Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.] [Designated as safety issue: No]

  The clinician's rating of disease severity as assessed by the Clinical Global Impression of Severity (CGI-S). CGI-S assesses the severity of the subject's condition on a 7-point scale ranging from 1 (normal, not at all ill) to 7 (among the most extremely ill); the 7 categories include the following: normal-shows no sign of illness, borderline ill, mildly (slightly) ill, moderately ill, markedly ill, severely ill, and among the most extremely ill. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

- Percentage of Participants With Improvement on the Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.] [Designated as safety issue: No]

  The clinician's rating of disease severity as assessed by the Clinical Global Impression of Severity (CGI-S). CGI-S assesses the severity of the subject's condition on a 7-point scale ranging from 1 (normal, not at all ill) to 7 (among the most extremely ill); the 7 categories include the following: normal-shows no sign of illness, borderline ill, mildly (slightly) ill, moderately ill, markedly ill, severely ill, and among the most extremely ill. Improvement is defined as at least 1 point improvement from baseline. Baseline was defined as the baseline value from the double -blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

- Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Score Values at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Baseline, Months 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.] [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 for work instability is low; 2 to 23, the risk is medium; and >23, the risk is high. Score range is 0 (lowest risk for work instability) to 36 (highest risk for work instability). Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

- Change From Baseline in the Medical Outcomes Study 6-Item Cognitive Functioning Scale (MOS-CF6) Total Score at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Baseline, Months 3, 6, 9, and 12 (or last postbaseline observation)] [Designated as safety issue: No]

  The MOS-CF 6 is an instrument to assess patient self-reported cognitive function. Items were selected to cover 6 relevant aspects of cognitive functioning as follows: confusion, concentration/thinking, attention, memory, reasoning, problem solving, and processing speed. The CF 6-item responses include 6 choices, ranging from "none of the time" to "all of the time." The CF-6 is scored by summing responses across the 6 items and converting the total to a 0- to 100-point scale, with higher scores indicating better cognitive functioning. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.

Enrollment:	49
Study Start Date:	August 2009
Study Completion Date:	January 2011
Primary Completion Date:	January 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Armodafinil Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.	Drug: Armodafinil Other Name: CEP-10953

Eligibility

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

Criteria

Patients enrolled in this study will be rollover patients (those who completed the previous double-blind efficacy study C10953/3067/ES/MN) and new patients (those who did not participate in the C10953/3067/ES/MN study).

Inclusion Criteria (for New Patients):

- The patient has a mild (Glasgow Coma Scale [GCS] score = 13-15) or moderate (GCS score = 9-12) closed traumatic brain injury (TBI) at the time of the injury, and the injury occurred 1 to 10 years prior to screening.
- The patient has a Glasgow Outcome Scale score of 5.
- The patient has an Epworth Sleepiness Scale (ESS) score of at least 10.
- The patient has a mean sleep latency on the Multiple Sleep Latency Test (MSLT) (average of 4 naps) of less than 8 minutes.
- The patient has a Clinical Global Impression of Severity of Illness (CGI-S) rating relating to their excessive sleepiness of 4 or more.
- The patient has 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 identified according to the first inclusion criterion.
- Written informed consent was obtained.
- If admitted to an in-patient treatment facility, the patient was discharged at least 1 month prior to the screening visit.
- The patient does 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 1 of those methods for the duration of the study (and for 30 days after participation in the study).
- The patient is 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 is willing and able to comply with study restrictions and attend regularly scheduled clinic visits as specified in the protocol.
- The patient has an 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 inhibitor [SSRIs] and serotonin and norepinephrine reuptake inhibitor [SNRIs]), 8 weeks (contraceptives), or 4 weeks (all other allowed medication) before the screening visit and is not likely to require a change in therapy for at least 12 weeks on the basis of the investigators' assessment.
- The patient has 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 has no other head injury fulfilling the criteria for TBI within ±1 year of the TBI identified according to the first inclusion criterion.
- The patient has a habitual bedtime between 2100 and 2400.

Inclusion Criteria (for Rollover Patients from Study C10953/3067/ES/MN):

- The patient has completed 12 weeks of double-blind treatment in Study C10953/3067/ES/MN.
- Written informed consent was obtained.
- Women of childbearing potential (not surgically sterile or 2 years postmenopausal), used a medically accepted method of contraception and agreed to continue use 1 of those methods for the duration of the study and for 30 days after participation in the study.

- The patient is in otherwise good health, as judged by the investigator, on the basis of a medical and psychiatric history, physical examination, ECG, serum chemistry, hematology, and urinalysis.
- The patient is willing and able to comply with study restrictions and to remain at the clinic for the required duration during the study period, and was willing to return to the clinic for the follow-up evaluation as specified in the protocol.

Exclusion Criteria (for New Patients):

- The patient has a history of 2 or more episodes of transient loss of consciousness without clear medical explanation, or has a history of known or suspected pseudo seizure (psychogenic seizure). Patients with a history of seizure or epilepsy may be eligible following discussion with the medical monitor.
- The patient requires, or is likely to require, treatment with anticonvulsant medication during the study; or has taken anticonvulsant medication within 6 months before the screening visit.
- The patient has an unstable or uncontrolled medical (including illnesses related to the cardiovascular, 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 has had neurosurgery involving the brain or brainstem.
- The patient has a history of schizophrenia, bipolar disorder, psychotic depression, or other psychotic episode.
- The patient has 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). Patients with any Axis II disorder, that in the opinion of the investigator, would affect patient participation in the study or full compliance with study procedures.
- The patient has a history of, or currently meets The International Classification of Sleep Disorders, Edition 2 (ICSD-2) criteria for any other sleep disorder associated with excessive daytime sleepiness; or the patient has a history of idiopathic hypersomnia, insomnia (requiring treatment), or sleep disorder before the development of the TBI.
- The patient has 85% or less sleep efficiency (sleep duration ÷ time in bed x 100%) as determined from Nocturnal Polysomnography (NPSG).
- The patient has any disorder that may have interfered with drug absorption, distribution, metabolism, or excretion.
- The patient has 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 is longer.
- The patient has a need for chronic pain medications.
- In the judgment of the investigator, the patient has a clinically significant deviation from normal in the physical examination.
- In the judgment of the investigator, the patient has any clinically significant ECG finding.
- The patient has a diagnosis of any type of dementia.
- The patient has a history of suicidal ideation (considered by the investigator to be of clinical significance), or is suicidal.
- The patient has a known hypersensitivity to armodafinil, racemic modafinil, or any component of the study drug tablets. Armodafinil tablets contained the following inactive ingredients: croscarmellose sodium, lactose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinized starch.
- The patient has 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 has a clinical laboratory test value(s) outside the range(s) specified in the protocol (or any other clinically significant laboratory abnormality), and the medical monitor had not provided written approval for study participation.
- The subject has 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 (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 has taken armodafinil, modafinil, or other stimulant medication for excessive sleepiness within 1 month of the screening visit.
- The patient is a pregnant or lactating woman.
- The patient is known to have tested positive for human immunodeficiency virus (HIV).
- The patient consumes an average of more than 600 mg of caffeine per day, including coffee, tea and/or other caffeine-containing beverages or food.
- The patient has used any investigational drug within 1 month before the screening visit.
- The patient is receiving workmen's compensation or was in active litigation with regard to TBI.
- The patient has a Self-Reported Hamilton Depression Rating Scale, 6 Item Version (S-HAM-D6) score of more than 4.

Exclusion Criteria (for Rollover Patients from Study C10953/3067/ES/MN):

- The patient has any clinically significant unstable or uncontrolled medical, surgical, or psychiatric conditions (treated or untreated) or may not be a suitable candidate for treatment with armodafinil, as judged by the investigator or medical monitor.
- The patient has current evidence of active psychosis, including stimulant-induced psychosis or mania.
- The patient has current evidence of non-medical substance use confirmed by results of a UDS.
- The patient has used any medications including OTC medicines disallowed by the protocol (except armodafinil use in study 3067) within 7 days or 5 half-lives of the drug and its active metabolites, whichever is longer.
- The patient has a clinically significant deviation from normal in the physical examination as judged by the investigator.
- The patient has a clinically significant laboratory abnormality, as judged by the investigator, without prior written approval by the medical monitor.

- The patient has hypersensitivity to armodafinil or modafinil, or any of the excipients of either.
- The patient is a pregnant or lactating woman.
- The patient is unlikely to comply with the study protocol, or is unsuitable for any other reason, as judged by the investigator.
- The patient consumes an average of more than 600 mg of caffeine per day (approximately equivalent to 5 or more cups of coffee), including coffee, tea, and/or other caffeine-containing beverages or food.

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: NCT00983437

Hide Study Locations

Locations

United States, Arizona

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

United States, Arkansas

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

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

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

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

United States, Florida

MD Clinical
Hallandale Beach, Florida, United States, 33009

Compass Research
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 Georgia
Atlanta, Georgia, United States, 30342

United States, Indiana

Goldpoint Clinical Research, LLC

Indianapolis, Indiana, United States, 46260

United States, Kentucky

Community Research
Crestview, Kentucky, United States, 45217

Kentucky Research Group
Louisville, Kentucky, United States, 40217

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Chevy Chase, Maryland, United States, 20815

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 Clinical Research
Lincoln, Nebraska, United States, 68510

United States, New York

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

United States, Ohio

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

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

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Oklahoma City, Oklahoma, United States, 73112

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

Consolidated Clinical Trials
Jefferson Hills, Pennsylvania, United States, 15025

United States, Texas

Houston Sleep Center
Houston, Texas, United States, 77024

Sleep Therapy and Research Center
San Antonio, Texas, United States, 78250

United States, Utah

Avastra Clinical Trials
Midvale, Utah, United States, 84047

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:	NCT00983437 History of Changes
Other Study ID Numbers:	**C10953/3069/ES/MN**
Study First Received:	September 9, 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	

ClinicalTrials.gov processed this record on May 04, 2015

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Trial record **1 of 1** for: C10953/3069/ES/MN

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Study to Evaluate the Safety, Tolerability, and Efficacy 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):
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First received: September 9, 2009
Last updated: August 14, 2013
Last verified: August 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: May 9, 2013

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Traumatic Brain Injury
Intervention:	Drug: Armodafinil

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
Of patients with excessive sleepiness associated with mild or moderate traumatic brain injury (TBI) who had completed study C10953/3067/ES/MN (NCT00893789) and were considered to be eligible for enrollment into the current study, 49 patients at 25 centers in the United States were enrolled. No new patients were screened for the study.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Of 49 participants enrolled, 2 were withdrawn before taking any study drug for reasons of protocol violation and noncompliance with study procedures, respectively.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Participant Flow: Overall Study

	Armodafinil
STARTED	**47**
Safety Analysis Set (SAS)	**47** [1]

Full Analysis Set (FAS)	**45** [2]
COMPLETED	**0** [3]
NOT COMPLETED	**47**
Adverse Event	**9**
Lack of Efficacy	**1**
Withdrawal by Subject	**8**
Noncompliance to Study Procedures	**1**
Lost to Follow-up	**2**
Other Reason	**26**

[1] Participants who received at least 1 dose of study drug were evaluable for safety.
[2] Participants had to have at least 1 postbaseline efficacy assessment to be evaluable for efficacy.
[3] Completed 12 months of treatment with armodafinil.

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.
Baseline Analysis Population includes 2 participants who were enrolled but not treated.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Baseline Measures

	Armodafinil
Number of Participants [units: participants]	**49**
Age [units: years] Mean (Standard Deviation)	**31.1 (10.15)**
Gender [units: participants]	
Female	**19**
Male	**30**
Race/Ethnicity, Customized [units: participants]	
White	**43**
Black	**3**
Asian	**2**
Other	**1**

Outcome Measures

Hide All Outcome Measures

1. Primary: Safety and Tolerability: Number of Participants With Adverse Events (AEs), Serious Adverse Events (SAEs), Deaths and Discontinuations Due to AEs [Time Frame: Assessed from Screening through end of treatment; median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Safety and Tolerability: Number of Participants With Adverse Events (AEs), Serious Adverse Events (SAEs), Deaths and Discontinuations Due to AEs
Measure Description	AE=any untoward medical occurrence 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 to study drug. Protocol-defined AEs=treatment-emergent adverse events associated with skin rash, hypersensitivity reaction, emergent suicidal ideation or suicide attempt, depression, psychosis, and seizure or suspected seizure were considered to be of potential clinical importance. DB=double-blind portion of the study (NCT00893789).
Time Frame	Assessed from Screening through end of treatment; median (full range) of treatment was 98 (5.0 to 326.0) days.
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 (study participants who received at least 1 dose of study drug)

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**47**
Safety and Tolerability: Number of Participants With Adverse Events (AEs), Serious Adverse Events (SAEs), Deaths and Discontinuations Due to AEs [units: participants]	
Any AE	**29**
Severe AEs	**0**
Treatment-related AEs	**17**
Deaths	**0**
SAEs (Other Than Deaths)	**1**
Discontinuations (DCs) Due to AEs	**7**
Protocol-defined AEs	**3**
DCs due to AEs with onset during DB phase	**2**

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

2. Primary: Safety and Tolerability: Concomitant Medication Usage In Participants Throughout the Study [Time Frame: Assessed from Screening through end of treatment; median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Safety and Tolerability: Concomitant Medication Usage In Participants Throughout the Study
Measure Description	Therapeutic classification of concomitant medications used by participants throughout the study. Participants are counted only once in each therapeutic class category.
Time Frame	Assessed from Screening through end of treatment; median (full range) of treatment was 98 (5.0 to 326.0) days.
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

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**47**
Safety and Tolerability: Concomitant Medication Usage In Participants Throughout the Study [units: participants]	
Participants receiving any concomitant medication	**39**
All other therapeutic products	**1**
Analgesics	**10**
Anesthetics	**1**
Anti-anemic preparations	**1**
Antibacterials for systemic use	**4**
Anti-emetics and antinauseants	**1**
Antigout preparations	**1**
Antihistamines for systemic use	**4**
Anti-inflammatory and antirheumatic products	**16**
Antimycotics for systemic use	**1**
Antithrombotic agents	**1**
Beta blocking agents	**1**
Cardiac therapy	**1**
Corticosteroids for systemic use	**1**
Cough and cold preparations	**2**
Drugs for acid-related disorders	**3**
Drugs for obstructive airway diseases	**3**
Drugs used in diabetes	**1**
General nutrients	**1**
Lipid-modifying agents	**11**
Nasal preparations	**4**

Other gynecologicals	**2**
Psychoanaleptics	**1**
Psycholeptics	**2**
Sex hormones and modulators of the genital system	**7**
Thyroid therapy	**1**
Unspecified herbal	**4**
Vitamins	**12**

No statistical analysis provided for Safety and Tolerability: Concomitant Medication Usage In Participants Throughout the Study

3. Primary: Safety and Tolerability: Number of Participants With Clinically Significant Serum Chemistry Test Results [Time Frame: Assessed at Screening, Months 6 and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Safety and Tolerability: Number of Participants With Clinically Significant Serum Chemistry Test Results
Measure Description	Criteria for clinically significant abnormal serum chemistry values: alanine aminotransferase (ALT) ≥3x upper limit of normal (ULN); aspartate aminotransferase (AST) ≥3x ULN; alkaline phosphatase ≥3x ULN; gamma-glutamyl transpeptidase (GGT) ≥3x ULN; lactate dehydrogenase (LDH) ≥3x ULN; blood urea nitrogen (BUN) ≥10.71 mmol/L; creatinine ≥177 µmol/L; uric acid, men ≥625 µmol/L, women ≥506 µmol/L; bilirubin (total) ≥34.2 µmol/L.
Time Frame	Assessed at Screening, Months 6 and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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 who had a baseline and at least one post-baseline value.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**38**
Safety and Tolerability: Number of Participants With Clinically Significant Serum Chemistry Test Results [units: participants]	
Participants with at least 1 abnormality (overall)	**3**
Blood Urea Nitrogen >=10.71	**2**
Uric Acid >=625 (male) or >=506 (female) µmol/L	**1**

No statistical analysis provided for Safety and Tolerability: Number of Participants With Clinically Significant Serum Chemistry Test Results

4. Primary: Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Vital Signs Measurements [Time Frame: Baseline, Week 2, Months 1, 2, 3, 6, 9, and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Vital Signs Measurements
Measure Description	Criteria for clinically significant abnormal vital signs values: pulse, ≥120 beats per minute (bpm) and increase from baseline of ≥15 bpm or ≤50 bpm and decrease from baseline of ≥15 bpm; systolic blood pressure, ≥180 mm Hg and increase from baseline of ≥20 mm Hg or ≤90 mm Hg and decrease from baseline of ≥20 mm Hg; diastolic blood pressure, ≥105 mm Hg and increase from baseline of ≥15 mm Hg or ≤50 mm Hg and decrease from baseline of ≥15 mm Hg; temperature >38.3º celsius (C) and change from baseline of ≥1.1°C. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline, Week 2, Months 1, 2, 3, 6, 9, and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**47**
Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Vital Signs Measurements [units: participants]	**0**

No statistical analysis provided for Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Vital Signs Measurements

5. Primary: Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Hematology Test Results [Time Frame: Assessed at Screening, Months 6 and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Hematology Test Results
Measure Description	Criteria for clinically significant abnormal hematology values: hematocrit, men <0.37 L/L or women <0.32 L/L; hemoglobin, men ≤115 g/L or women ≤95 g/L; white blood cell (WBC) count ≤3x10^9/L or ≥20x10^9/L; eosinophils ≥10%; absolute neutrophil count (ANC) ≤1x10^9/L; platelet count ≤75x10^9/L or ≥700x10^9/L.
Time Frame	Assessed at Screening, Months 6 and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**47**
Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Hematology Test Results [units: participants]	**0**

No statistical analysis provided for Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Hematology Test Results

6. Primary: Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Urinalysis Results [Time Frame: Baseline, Months 6 and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Urinalysis Results
Measure Description	Criteria for clinically significant abnormal urinalysis values: blood (hemoglobin) ≥2 unit increase from baseline; glucose ≥2 unit increase from baseline; ketones ≥2 unit increase from baseline; total protein ≥2 unit increase from baseline. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline, Months 6 and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**47**
Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Urinalysis Results [units: participants]	**0**

No statistical analysis provided for Safety and Tolerability: Number of Participants With Clinically Significant Abnormal Urinalysis Results

7. Primary: Safety and Tolerability: Number of Participants With Notable Blood Pressure Values Per World Health Organization Criteria [Time Frame: Baseline, Week 2, Months 1, 2, 3, 6, 9, and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Safety and Tolerability: 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. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline, Week 2, Months 1, 2, 3, 6, 9, and 12 (or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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; participants with a baseline and postbaseline value.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**45**
Safety and Tolerability: Number of Participants With Notable Blood Pressure Values Per World Health Organization Criteria [units: participants]	
Participants with at least 1 notable BP value	**6**
Sitting systolic BP >=140 mm Hg + Increase >=10%	**4**
Sitting diastolic BP >=90 mm Hg + Increase >=10%	**3**

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

8. Primary: Safety and Tolerability: Electrocardiogram (ECG) Findings Shifts From Baseline to Overall [Time Frame: Baseline through Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Safety and Tolerability: 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. Any ECG finding that was judged by the investigator as a clinically meaningful change (worsening) compared to baseline was recorded as an adverse event. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline through Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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; only those participants with both baseline and endpoint ECG findings are summarized.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**35**
Safety and Tolerability: Electrocardiogram (ECG) Findings Shifts From Baseline to Overall [units: participants]	
Normal at BL → Normal Overall	**17**
Normal at BL→ Abnormal Overall	**4**
Abnormal at BL→ Normal Overall	**3**
Abnormal at BL → Abnormal Overall	**11**

No statistical analysis provided for Safety and Tolerability: Electrocardiogram (ECG) Findings Shifts From Baseline to Overall

9. Primary: Safety and Tolerability: Physical Examination Findings Shifts From Baseline to Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Baseline through Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Safety and Tolerability: Physical Examination Findings Shifts From Baseline to Endpoint (Month 12 or Last Postbaseline Observation)
Measure Description	Number of participants with shifts from normal/abnormal physical examination findings at baseline (BL) to (→) normal/abnormal findings at endpoint (EP). 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. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline through Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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; only those participants with both baseline and endpoint physical examination findings are summarized.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**39**
Safety and Tolerability: Physical Examination Findings Shifts From Baseline to Endpoint (Month 12 or Last Postbaseline Observation) [units: participants]	
General Appearance: Normal at BL→Normal at EP	**37**
General Appearance: Normal at BL→ Abnormal at EP	**2**
General Appearance: Abnormal at BL→ Normal at EP	**0**
General Appearance: Abnormal at BL→Abnormal at EP	**0**
HEENT: Normal at BL→Normal at EP	**37**
HEENT: Normal at BL→Abnormal at EP	**1**
HEENT: Abnormal at BL→Normal at EP	**1**
HEENT: Abnormal at BL→Abnormal at EP	**0**
Chest/Lungs: Normal at BL→Normal at EP	**39**
Chest/Lungs: Normal at BL→Abnormal at EP	**0**
Chest/Lungs: Abnormal at BL→Normal at EP	**0**
Chest/Lungs: Abnormal at BL→Abnormal at EP	**0**
Heart: Normal at BL→Normal at EP	**38**
Heart: Normal at BL→Abnormal at EP	**1**
Heart: Abnormal at BL→Normal at EP	**0**
Heart: Abnormal at BL→Abnormal at EP	**0**
Abdomen: Normal at BL→Normal at EP	**38**
Abdomen: Normal at BL→Abnormal at EP	**1**
Abdomen: Abnormal at BL→Normal at EP	**0**
Abdomen: Abnormal at BL→Abnormal at EP	**0**
Musculoskeletal: Normal at BL→Normal at EP	**38**
Musculoskeletal: Normal at BL→Abnormal at EP	**1**
Musculoskeletal: Abnormal at BL→Normal at EP	**0**
Musculoskeletal: Abnormal at BL→Abnormal at EP	**0**
Skin: Normal at BL→Normal at EP	**35**
Skin: Normal at BL→Abnormal at EP	**0**
Skin: Abnormal at BL→Normal at EP	**0**
Skin: Abnormal at BL→Abnormal at EP	**4**
Lymph Nodes: Normal at BL→Normal at EP	**34**
Lymph Nodes: Normal at BL→Abnormal at EP	**0**
Lymph Nodes: Abnormal at BL→Normal at EP	**1**
Lymph Nodes: Abnormal at BL→Abnormal at EP	**0**
Neurological: Normal at BL→Normal at EP	**37**
Neurological: Normal at BL→Abnormal at EP	**1**
Neurological: Abnormal at BL→Normal at EP	**1**
Neurological: Abnormal at BL→Abnormal at EP	**0**

No statistical analysis provided for Safety and Tolerability: Physical Examination Findings Shifts From Baseline to Endpoint (Month 12 or Last Postbaseline Observation)

10. Primary: Number of Participants Answering "Yes" to Any Question on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation) [Time Frame: Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Number of Participants Answering "Yes" to Any Question on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation)
Measure Description	The percentage of participants answering 'yes' to any of the 9 yes/no questions about suicidal behaviors, ideations, and acts at given time points are presented. The C-SSRS captures occurrence, severity, and frequency of suicide-related thoughts and behaviors since last visit (SLV). Questions included the presence (yes) or absence (no) 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	Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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; n=number of participants with nonmissing value at given time point.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**47**
Number of Participants Answering "Yes" to Any Question on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation) [units: participants]	
Week 2 (n=18), yes to any question	**0**
Month 1 (n=18), yes to any question	**0**
Month 2 (n=18), yes to any question	**0**
Month 3 (n=13), yes to any question	**0**
Month 6 (n=10), yes to any question	**0**
Month 9 (n=4), yes to any question	**0**
Endpoint (n=36), yes to 'Wish to Be Dead' question	**1**
Endpoint (n=36), yes to all other questions	**0**

No statistical analysis provided for Number of Participants Answering "Yes" to Any Question on the Columbia-Suicide Severity Rating Scale Since Last Visit Version (C-SSRS SLV) at Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation)

11. Primary: Change From Baseline in the Total Score From the Self-Reported Hamilton Depression Rating Scale, 6 Item Version (S-HAM-D6) at Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation) [Time Frame: Baseline, Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Primary
Measure Title	Change From Baseline in the Total Score From the Self-Reported Hamilton Depression Rating Scale, 6 Item Version (S-HAM-D6) at Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation)
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. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline, Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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 value; n=number of participants with baseline and postbaseline value at given time point.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**13**
Change From Baseline in the Total Score From the Self-Reported Hamilton Depression Rating Scale, 6 Item Version (S-HAM-D6) at Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation) [units: units on a scale] Mean (Standard Deviation)	
Baseline (BL; n=13)	**1.4 (1.33)**
Change from BL at Week 2 (n=13)	**0.9 (3.43)**
Change from BL at Month 1 (n=12)	**0.2 (2.41)**
Change from BL at Month 2 (n=9)	**0.0 (2.35)**
Change from BL at Month 3 (n=1)	**-1.0 (NA)** [1]
Change from BL at Month 6 (n=0)	**NA (NA)** [2]
Change from BL at Month 9 (n=0)	**NA (NA)** [2]
Change from BL at Endpoint (n=13)	**0.0 (2.65)**

[1] Only 1 participant measured.
[2] No participants had available measurements at this time point.

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 Week 2, Months 1, 2, 3, 6, 9, and Endpoint (Month 12, or Last Postbaseline Observation)

12. Secondary: Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Baseline, Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Secondary
Measure Title	Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)
Measure Description	The participant'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. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline, Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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 = participants in the Safety Analysis Set who had at least 1 post-baseline efficacy assessment; n=number of participants with value at baseline and given time point.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**45**
Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [units: units on a scale] Mean (Standard Deviation)	
Baseline (BL; n=45)	**14.8 (2.60)**
Change from BL at Week 2 (n=41)	**-8.0 (4.42)**
Change from BL at Month 1 (n=35)	**-8.5 (4.37)**
Change from BL at Month 2 (n=30)	**-9.0 (3.56)**
Change from BL at Month 3 (n=22)	**-9.0 (3.53)**
Change from BL at Month 6 (n=11)	**-10.0 (3.26)**
Change from BL at Month 9 (n=4)	**-10.3 (4.79)**
Change from BL at Endpoint (n=45)	**-9.0 (4.48)**

No statistical analysis provided for Change From Baseline in Epworth Sleepiness Scale (ESS) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint

(Month 12 or Last Postbaseline Observation)

13. Secondary: Change From Baseline in Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Baseline, Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Secondary
Measure Title	Change From Baseline in Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)
Measure Description	The clinician's rating of disease severity as assessed by the Clinical Global Impression of Severity (CGI-S). CGI-S assesses the severity of the subject's condition on a 7-point scale ranging from 1 (normal, not at all ill) to 7 (among the most extremely ill); the 7 categories include the following: normal-shows no sign of illness, borderline ill, mildly (slightly) ill, moderately ill, markedly ill, severely ill, and among the most extremely ill. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline, Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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 = participants in the Safety Analysis Set who had at least 1 post-baseline efficacy assessment; n=number of participants with value at baseline and given time point.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**45**
Change From Baseline in Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [units: units on a scale] Mean (Standard Deviation)	
Baseline (BL; n=45)	**4.4 (0.53)**
Change from BL at Week 2 (n=41)	**-1.9 (1.04)**
Change from BL at Month 1 (n=35)	**-2.1 (1.09)**
Change from BL at Month 2 (n=30)	**-2.6 (0.81)**
Change from BL at Month 3 (n=22)	**-2.4 (0.73)**
Change from BL at Month 6 (n=11)	**-2.5 (1.29)**
Change from BL at Month 9 (n=4)	**-3.3 (0.96)**
Change from BL at Endpoint (n=45)	**-2.2 (1.15)**

No statistical analysis provided for Change From Baseline in Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)

14. Secondary: Percentage of Participants With Improvement on the Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Secondary
Measure Title	Percentage of Participants With Improvement on the Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)
Measure Description	The clinician's rating of disease severity as assessed by the Clinical Global Impression of Severity (CGI-S). CGI-S assesses the severity of the subject's condition on a 7-point scale ranging from 1 (normal, not at all ill) to 7 (among the most extremely ill); the 7 categories include the following: normal-shows no sign of illness, borderline ill, mildly (slightly) ill, moderately ill, markedly ill, severely ill, and among the most extremely ill. Improvement is defined as at least 1 point improvement from baseline. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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 = participants in the Safety Analysis Set who had at least 1 post-baseline efficacy assessment; n=number of participants with value at baseline and given time point.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**45**
Percentage of Participants With Improvement on the Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [units: percentage of participants]	
Improved at Week 2 (n=41)	**95**
Not Improved at Week 2 (n=41)	**5**
Improved at Month 1 (n=35)	**97**
Not Improved at Month 1 (n=35)	**3**
Improved at Month 2 (n=30)	**100**
Not Improved at Month 2 (n=30)	**0**
Improved at Month 3 (n=22)	**100**
Not Improved at Month 3 (n=22)	**0**
Improved at Month 6 (n=11)	**91**
Not Improved at Month 6 (n=11)	**9**
Improved at Month 9 (n=4)	**100**
Not Improved at Month 9 (n=4)	**0**
Improved at Endpoint (n=45)	**93**

Not Improved at Endpoint (n=45)	**7**

No statistical analysis provided for Percentage of Participants With Improvement on the Clinical Global Impression of Severity of Illness (CGI-S) at Week 2 and Months 1, 2, 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)

15. Secondary: Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Score Values at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Baseline, Months 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.]

Measure Type	Secondary
Measure Title	Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Score Values at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)
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 for work instability is low; 2 to 23, the risk is medium; and >23, the risk is high. Score range is 0 (lowest risk for work instability) to 36 (highest risk for work instability). Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline, Months 3, 6, 9, and Endpoint (Month 12 or last postbaseline observation); median (full range) of treatment was 98 (5.0 to 326.0) days.
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 (those in the Safety Analysis Set with at least 1 post-baseline efficacy assessment) with a TBI-WIS score at baseline; n=number of participants with value at baseline and given time point.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**34**
Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Score Values at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [units: units on a scale] Mean (Standard Deviation)	
Baseline (BL; n=34)	**9.6 (6.93)**
Change from BL at Month 3 (n=19)	**-3.1 (5.87)**
Change from BL at Month 6 (n=10)	**-2.5 (7.32)**
Change from BL at Month 9 (n=3)	**-7.3 (2.52)**
Change from BL at Endpoint (n=34)	**-4.6 (6.52)**

No statistical analysis provided for Change From Baseline in Traumatic Brain Injury - Work Instability Scale (TBI-WIS) Score Values at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)

16. Secondary: Change From Baseline in the Medical Outcomes Study 6-Item Cognitive Functioning Scale (MOS-CF6) Total Score at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation) [Time Frame: Baseline, Months 3, 6, 9, and 12 (or last postbaseline observation)]

Measure Type	Secondary
Measure Title	Change From Baseline in the Medical Outcomes Study 6-Item Cognitive Functioning Scale (MOS-CF6) Total Score at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)
Measure Description	The MOS-CF 6 is an instrument to assess patient self-reported cognitive function. Items were selected to cover 6 relevant aspects of cognitive functioning as follows: confusion, concentration/thinking, attention, memory, reasoning, problem solving, and processing speed. The CF 6-item responses include 6 choices, ranging from “none of the time” to “all of the time.” The CF-6 is scored by summing responses across the 6 items and converting the total to a 0- to 100-point scale, with higher scores indicating better cognitive functioning. Baseline was defined as the baseline value from the double-blind study C10953/3067/ES/MN (NCT00893789) from which the participants entered into this open-label study.
Time Frame	Baseline, Months 3, 6, 9, and 12 (or last postbaseline observation)
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.
Changes from baseline in MOS-CF6 total score were not summarized. This assessment was not performed in study C10953/3067/ES/MN (NCT00893789); therefore, the data obtained at screening for the current study would represent true baseline data only for new participants, of which there were none.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Measured Values

	Armodafinil
Number of Participants Analyzed [units: participants]	**0**
Change From Baseline in the Medical Outcomes Study 6-Item Cognitive Functioning Scale (MOS-CF6) Total Score at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)	

No statistical analysis provided for Change From Baseline in the Medical Outcomes Study 6-Item Cognitive Functioning Scale (MOS-CF6) Total Score at Months 3, 6, 9, and Endpoint (Month 12 or Last Postbaseline Observation)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From Screening through end of treatment; median (full range) of treatment was 98 (5.0 to 326.0) days.
Additional Description	No text entered.

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Serious Adverse Events

	Armodafinil

Total, serious adverse events	
# participants affected / at risk	**1/47 (2.13%)**
Psychiatric disorders	
Psychotic Disorder † 1	
# participants affected / at risk	**1/47 (2.13%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	From Screening through end of treatment; median (full range) of treatment was 98 (5.0 to 326.0) days.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Armodafinil	Armodafinil tablets 150 mg or 250 mg administered orally, once daily in the morning.

Other Adverse Events

	Armodafinil
Total, other (not including serious) adverse events	
# participants affected / at risk	**29/47 (61.70%)**
Gastrointestinal disorders	
Nausea † 1	
# participants affected / at risk	**3/47 (6.38%)**
Dry mouth † 1	
# participants affected / at risk	**2/47 (4.26%)**
General disorders	
Feeling jittery † 1	
# participants affected / at risk	**2/47 (4.26%)**
Infections and infestations	
Upper respiratory tract infection † 1	
# participants affected / at risk	**4/47 (8.51%)**
Injury, poisoning and procedural complications	
Muscle strain † 1	
# participants affected / at risk	**2/47 (4.26%)**
Investigations	
Weight decreased † 1	
# participants affected / at risk	**2/47 (4.26%)**
Musculoskeletal and connective tissue disorders	
Muscle tightness † 1	

# participants affected / at risk	**2/47 (4.26%)**
Pain in extremity † 1	
# participants affected / at risk	**2/47 (4.26%)**
Nervous system disorders	
Headache † 1	
# participants affected / at risk	**7/47 (14.89%)**
Psychiatric disorders	
Insomnia † 1	
# participants affected / at risk	**3/47 (6.38%)**
Anxiety † 1	
# participants affected / at risk	**2/47 (4.26%)**

† 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 the 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)
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