A221101

A Phase III Randomized, Double-Blind Placebo Controlled Study of Armodafinil (Nuvigil®) To Reduce Cancer-Related Fatigue in Patients With High Grade Glioma

ClinicalTrials.gov Identifier: NCT01781468

Study Background

Trial Description

This randomized phase III trial studies armodafinil to see how well it works in reducing cancer-related fatigue in patients with high grade glioma. Armodafinil may help relieve fatigue in patients with high grade glioma.

Arms:

Arm I: (Experimental): Patients receive 150 mg armodafinil orally every day in the morning for 8 weeks.

Arm II: (Placebo Comparator): Patients receive placebo orally every day in the morning for 8 weeks.

Arm III: (Experimental): Patients receive 250 mg armodafinil orally every day in the morning for 8 weeks.

Objectives:

Patients experiencing fatigue related to cancer will be asked to take part in this study. Cancer-related fatigue is a very common symptom in patients with cancer. Patients will receive armodafinil or placebo. Please see the "Arms" section for more details regarding the treatment assignments. The primary objective of this study is to determine preliminary efficacy measured by patient reported fatigue Brief Fatigue Inventory (BFI) at 8 weeks of two doses (150 mg and 250 mg) of armodafinil in treating moderate fatigue compared to placebo in patients with high grade glioma. The secondary objectives of the study are listed below.

1. To evaluate the tolerability at 8 weeks of 150 mg and 250 mg armodafinil in this patient population.
2. To assess the effect of armodafinil at 8 weeks on cognitive function in patients with high grade glioma.
3. To assess the impact of armodafinil on global quality of life and other fatigue endpoints in this patient population with high grade glioma.

4. Explore the correlation between the BFI, Patient-Reported Outcomes Measurement Information System (PROMIS), and Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) measures, as well as, the relationship of fatigue and cognitive difficulties. Patients will receive armodafinil or placebo for a total of 8 weeks.

Study Milestones:

Start date: June 2013

Primary Completion Date: May 2019

Publication Information:

Analysis Type: Primary

PubMed ID: 34882169

Citation: JAMA Oncol. 2021 Dec 9;e215948. doi: 10.1001/jamaoncol.2021.5948.

Associated Datasets: NCT01781468-D1-Dataset.csv (final_analysis), NCT01781468-D2-Dataset.csv (final_cytox)

Dataset Information:

Dataset Name: NCT01781468-D1-Dataset.csv (final_analysis)

Description: Dataset NCT01781468-D1-Dataset.csv (final_analysis) is one of 2 datasets associated with PubMed ID 34882169. This dataset contains data presented in the Consort Diagram, Table 1, Table 2, Table 3, eTable 1, eTable 2, eTable 3, eTable 4, and eTable 5.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

NCT01781468-D1-Dataset.csv (final_analysis) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Age (years)	AGE		
Age group (years)	AGE_G	< 60, >= 60	There are four instances where age group does not match the data in variable *AGE*. *AGE_G* is provided in this dataset since it was used as a stratification factor, as indicated in the corresponding publication.
Worst fatigue question score of the Brief Fatigue Inventory (BFI) (inclusion criterion >= 6)	BFI	4, 6, 7, 8, 9, 10	
Is this a woman of childbearing potential?	CBPOT	No, Yes	
Concomitant Chemotherapy	CONCHEM	No, Yes	
Corticosteroid Use	CORTICOS	No, Yes	

LABEL	NAME	ELEMENTS	COMMENTS
ECOG Performance Status	ECOGPS	0, 1, 2, 3	
Gender	GENDER	Female, Male	
Arm	ARM	Armodafinil 150 mg, Armodafinil 250 mg, Placebo	
Prior Concurrent Chemotherapy Cancer Therapy	CON_RX	No, Yes	
Prior Chemotherapy Cancer Therapy	PRIOR_RX	No, Yes	
Status of Primary Tumor	TUM_STAT	Recurrent, Resected with known residual, Resected with no residual, Unresected	
Reason End Treatment	ENDATRSN	Adverse Events/Side Effects/Complications; Alternative Therapy; Death On Study; Disease Progression, Relapse During Active Treatment; Disease Progression Before Active Treatment; Other; Patient Off-Treatment For Other Complicating Disease; Patient Withdrawal/Refusal After Beginning Protocol Therapy; Patient Withdrawal/Refusal Prior To Beginning Protocol Therapy; Treatment Completed Per Protocol Criteria	
USUAL level of fatigue during the past 24 hours (Baseline)	bfi2_bsl	1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
USUAL level of fatigue during the past 24 hours (End of Week 4)	bfi2_wk4	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	

LABEL	NAME	ELEMENTS	COMMENTS
USUAL level of fatigue during the past 24 hours (End of Week 8)	bfi2_wk8	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
Change in USUAL level of fatigue during the past 24 hours from Baseline to End of Week 8	bfi2_wk8bsl	-1, -2, -3, -4, -5, -6, -7, -8, -9, 0, 1, 2, 3, 4, 5, 7	
Clinically Meaningful Improvement from Baseline to End of Week 8	response_wk8	No, Yes	
Change in USUAL level of fatigue during the past 24 hours from Baseline to End of Week 4	bfi2_wk4bsl	-1, -2, -3, -4, -5, -6, -7, -8, 0, 1, 2, 3, 4, 6, 7	
Change in fatigue right NOW from Baseline to End of Week 4	bfi1_wk4bsl	-1, -2, -3, -4, -5, -6, -7, -8, -9, 0, 1, 2, 3, 4, 5, 6	
Change in fatigue right NOW from Baseline to End of Week 8	bfi1_wk8bsl	-1, -2, -3, -4, -5, -6, -7, -8, -9, 0, 1, 2, 3, 4, 5, 6, 7	
Change in WORST level of fatigue during the past 24 hours from Baseline to End of Week 4	bfi3_wk4bsl	-1, -2, -3, -4, -5, -6, -7, -8, -9, -10, 0, 1, 2, 3, 4, 5, 6	
Change in WORST level of fatigue during the past 24 hours from Baseline to End of Week 8	bfi3_wk8bsl	-1, -2, -3, -4, -5, -6, -7, -8, -9, 0, 1, 2, 3, 4, 5, 6	
Global Fatigue Score (Baseline)	avg_bfi_bsl		
Change in Global Fatigue Score from Baseline to End of Week 4	avgbfi_wk4bsl		

LABEL	NAME	ELEMENTS	COMMENTS
Change in Global Fatigue Score from Baseline to End of Week 8	avgbfi_wk8bsl		
Total Raw PROMIS Fatigue Score (Baseline)	tot_fatig_bsl		
Change in Total Raw PROMIS Fatigue Score from Baseline to End of Week 4	totfatig_wk4bsl		
Change in Total Raw PROMIS Fatigue Score from Baseline to End of Week 8	totfatig_wk8bsl		
Total Raw LASA Score (Baseline)	tot_lasa_bsl		
Change in Total Raw LASA Score from Baseline to End of Week 4	totlasa_wk4bsl		
Change in Total Raw LASA Score from Baseline to End of Week 8	totlasa_wk8bsl		
Perceived Cognitive Impairments Subscale (Baseline)	score_cogpci_bsl		
Impact of Perceived Cognitive Impairments on Quality of Life Subscale (Baseline)	score_cogqol_bsl	0, 1, 1.3333, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16	
Perceived Cognitive Abilities Subscale (Baseline)	score_cogpca_bsl		
Change in Perceived Cognitive Impairments Subscale from Baseline to End of Week 4	cogpci_wk4bsl		

LABEL	NAME	ELEMENTS	COMMENTS
Change in Perceived Cognitive Impairments Subscale from Baseline to End of Week 8	cogpci_wk8bsl		
Change in Impact of Perceived Cognitive Impairments on Quality of Life Subscale from Baseline to End of Week 4	cogqol_wk4bsl		
Change in Impact of Perceived Cognitive Impairments on Quality of Life Subscale from Baseline to End of Week 8	cogqol_wk8bsl		
Change in Perceived Cognitive Abilities Subscale from Baseline to End of Week 4	cogpca_wk4bsl		
Change in Perceived Cognitive Abilities Subscale from Baseline to End of Week 8	cogpca_wk8bsl		
Total Leisure Activity Score (Baseline)	tot_godin1_bsl		
Change in Total Leisure Activity Score from Baseline to End of Week 4	totgodin1_wk4bsl		
Change in Total Leisure Activity Score from Baseline to End of Week 8	totgodin1_wk8bsl		

LABEL	NAME	ELEMENTS	COMMENTS
Change in engagement of any regular activity long enough to work up a sweat from Baseline to End of Week 4	godin2_wk4bsl	-1, -2, 0, 1, 2	
Change in engagement of any regular activity long enough to work up a sweat from Baseline to End of Week 8	godin2_wk8bsl	-1, -2, 0, 1, 2	
What was the severity of your fatigue tiredness or lack of energy at its WORST in the last 7 days? (Baseline)	outcome1_bsl	1, 2, 3, 4, 5	
How much did fatigue tiredness or lack of energy INTERFERE with your usual or daily activities in the last 7 days? (Baseline)	outcome2_bsl	1, 2, 3, 4, 5	
What was the SEVERITY of your problems with concentration at their WORST in the last 7 days? (Baseline)	outcome3_bsl	1, 2, 3, 4, 5	
How much did problems with concentration INTERFERE with your usual or daily activities in the last 7 days? (Baseline)	outcome4_bsl	1, 2, 3, 4, 5	
What was the SEVERITY of your problems with memory at their WORST in the last 7 days? (Baseline)	outcome5_bsl	1, 2, 3, 4, 5	

LABEL	NAME	ELEMENTS	COMMENTS
How much did problems with memory INTERFERE with your usual or daily activities in the last 7 days? (Baseline)	outcome6_bsl	1, 2, 3, 4, 5	
Change in SEVERITY of fatigue, tiredness, or lack of energy at its WORST in the last 7 days from Baseline to End of Week 4	outcome1_wk4bsl	-1, -2, -3, -4, 0, 1, 2	
Change in SEVERITY of fatigue, tiredness, or lack of energy at its WORST in the last 7 days from Baseline to End of Week 8	outcome1_wk8bsl	-1, -2, -3, 0, 1, 2	
Change in INTERFERENCE of fatigue, tiredness, or lack of energy with usual or daily activities in the last 7 days from Baseline to End of Week 4	outcome2_wk4bsl	-1, -2, -3, -4, 0, 1, 2, 3	
Change in INTERFERENCE of fatigue, tiredness, or lack of energy with usual or daily activities in the last 7 days from Baseline to End of Week 8	outcome2_wk8bsl	-1, -2, -3, -4, 0, 1, 2	
Change in SEVERITY of problems with concentration at its WORST in the last 7 days from Baseline to End of Week 4	outcome3_wk4bsl	-1, -2, -3, -4, 0, 1, 2, 3	

LABEL	NAME	ELEMENTS	COMMENTS
Change in SEVERITY of problems with concentration at its WORST in the last 7 days from Baseline to End of Week 8	outcome3_wk8bsl	-1, -2, -3, -4, 0, 1, 2	
Change in INTERFERENCE of problems with concentration with usual or daily activities in the last 7 days from Baseline to End of Week 4	outcome4_wk4bsl	-1, -2, -3, -4, 0, 1, 2, 3, 4	
Change in INTERFERENCE of problems with concentration with usual or daily activities in the last 7 days from Baseline to End of Week 8	outcome4_wk8bsl	-1, -2, -3, -4, 0, 1, 2, 3	
Change in SEVERITY of problems with memory at their WORST in the last 7 days from Baseline to End of Week 4	outcome5_wk4bsl	-1, -2, -3, -4, 0, 1, 2, 3	
Change in SEVERITY of problems with memory at their WORST in the last 7 days from Baseline to End of Week 8	outcome5_wk8bsl	-1, -2, -3, -4, 0, 1, 2	
Change in INTERFERENCE of problems with memory with usual or daily activities in the last 7 days from Baseline to End of Week 4	outcome6_wk4bsl	-1, -2, -3, 0, 1, 2, 3, 4	

LABEL	NAME	ELEMENTS	COMMENTS
Change in INTERFERENCE of problems with memory with usual or daily activities in the last 7 days from Baseline to End of Week 8	outcome6_wk8bsl	-1, -2, -3, 0, 1, 2	
Receipt of Treatment	tx	0 = No, 1 = Yes	
Race	race	Non-White, White	
Ethnicity	ethnicity	Hispanic or Latino, Not Hispanic or Latino	
Days from End of Previous Radiotherapy to Registration	rtend2reg_days		
Months from End of Previous Radiotherapy to Registration	rtend2reg_6mo	< 6 months, >= 6 months	
Baseline Z Score: Symbol Digit Modality Test	zsdmt_bsl		
Baseline Z Score: TMTA (Trail Making Test part A) time to complete	ztmatime_bsl		
Baseline Z Score: TMTB (Trail Making Test part B) time to complete	ztmbtime_bsl		
Baseline Z Score: COWAT (Controlled Oral Word association test) Total	zcowatot_bsl		
Diff in Z score from Baseline to End of Week 4: Symbol Digit Modality Test	dsdmt_wk4bsl		
Diff in Z score from Baseline to End of Week 4: TMTA time to complete	dtmatime_wk4bsl		

LABEL	NAME	ELEMENTS	COMMENTS
Diff in Z score from Baseline to End of Week 4: TMTB time to complete	dtmbtime_wk4bsl		
Diff in Z score from Baseline to End of Week 4: COWAT Total	dcowatot_wk4bsl		
Deterioration from Baseline to End of Week 4: Symbol Digit Modality Test	isdmt_wk4bsl	1 = Deterioration, 2 = No change, 3 = Improved	
Deterioration from Baseline to End of Week 4: TMTA time to complete	itmatime_wk4bsl	1 = Deterioration, 2 = No change, 3 = Improved	
Deterioration from Baseline to End of Week 4: TMTB time to complete	itmbtime_wk4bsl	1 = Deterioration, 2 = No change, 3 = Improved	
Deterioration from Baseline to End of Week 4: COWAT Total	icowatot_wk4bsl	1 = Deterioration, 2 = No change, 3 = Improved	
Diff in Z score from Baseline to End of Week 8: Symbol Digit Modality Test	dsdmt_wk8bsl		
Diff in Z score from Baseline to End of Week 8: TMTA time to complete	dtmatime_wk8bsl		
Diff in Z score from Baseline to End of Week 8: TMTB time to complete	dtmbtime_wk8bsl		
Diff in Z score from Baseline to End of Week 8: COWAT Total	dcowatot_wk8bsl		

LABEL	NAME	ELEMENTS	COMMENTS
Deterioration from Baseline to End of Week 8: Symbol Digit Modality Test	isdmt_wk8bsl	1 = Deterioration, 2 = No change, 3 = Improved	
Deterioration from Baseline to End of Week 8: TMTA time to complete	itmatime_wk8bsl	1 = Deterioration, 2 = No change, 3 = Improved	
Deterioration from Baseline to End of Week 8: TMTB time to complete	itmbtime_wk8bsl	1 = Deterioration, 2 = No change, 3 = Improved	
Deterioration from Baseline to End of Week 8: COWAT Total	icowatot_wk8bsl	1 = Deterioration, 2 = No change, 3 = Improved	
Neurocognitive Progression (drop of 1 SD in at least 1 test) from Baseline to End of Week 4	cpg_stat_wk4bsl	1 = No, 2 = Yes	
Neurocognitive Progression (drop of 1 SD in at least 1 test) from Baseline to End of Week 8	cpg_stat_wk8bsl	1 = No, 2 = Yes	
End of Treatment Reason: Other Specify	endatothr	Hospice, Hospitalization, Ineligible, Physician discretion, Started other drug (Ritalin)	
Excluded from primary end point analysis	exclude	No, Yes	
Ineligible Patients	inelig	0 = No, 1 = Yes	
Months from end of prior chemotherapy to registration	priorrx2reg_months		
Patient ID	pat_id		