# 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-D2-Dataset.csv (final_cytox)

Description: Dataset NCT01781468-D2-Dataset.csv (final_cytox) is one of 2 datasets associated with PubMed ID 34882169. This dataset contains data presented in Table 4.

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-D2-Dataset.csv (final_cytox) Data Dictionary:

| LABEL | NAME | ELEMENTS | COMMENTS |
|---|---|---|---|
| Cycle | CYCLE | 1, 2 | |
| Grade | GRADE | 1, 2, 3, 4, 5 | |
| Relationship Study Meds | REL_SMED | DEFINITE, NOT RELATED, POSSIBLE, PROBABLE, UNLIKELY | |
| MedDRA System Organ class (version 12.0) | SOC | Blood and lymphatic sys disord; Ear and labyrinth disorders; Gastrointestinal disorders; Gen disord and admin site cond; Infections and infestations, Inj, pois and proced complic; Investigations; Metabol and nutrition disord; Musculosk and conn tiss disord; Neoplsm benign, mal and unspec; Nervous system disorders; Psychiatric disorders; Respirat, thor, mediast disord; Skin and subcutan tiss disord; Vascular disorders | |
| CTCAE term (version 4) | TOXICITY | | |
| Patient ID | pat_id | | |