

Pilot study of modafinil for treatment of neurobehavioral dysfunction and fatigue in adult patients with brain tumors.
Sub-category: [CNS Tumors](#)
Category: Central Nervous System Tumors

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Abstract: **Background:** Patients with brain cancer develop neurobehavioral dysfunction and fatigue that compromise their performance of daily activities. We report results from evaluating the efficacy and safety of modafinil treatment for tumor/therapy sequelae in this medically fragile patient population. **Methods:** Patients: 21-65 years old with primary malignant disease or nonmalignant cerebral tumors treated with neurosurgical resection, radiotherapy, and/or chemotherapy. Clinical Global Impression of Severity ratings of mild to severe attention/memory impairment and/or fatigue. Measures: Trail Making (TM) A and B, Symbol Digit Modalities (SDM), Verbal Fluency (VF), Hamilton Depression Scale (HAM-D), Fatigue Severity Scale (FSS), Visual Analogue Fatigue Scale (VAFS), Modified Fatigue Impact Scale (MFIS). Design: Double-blind dose-controlled randomization (200 or 400 mg/day modafinil in divided doses) 3 wks; Washout 1wk; Open label extension 8 wks. Statistical analyses: Changes from baseline at scheduled visits (1, 3, 4, 8, 12 wks) using paired t-tests or Wilcoxon Signed Rank tests as appropriate. **Results:** Thirty patients, 63% male, mean age (SD) = 45.3 (11.7) yrs were accrued from 6/03-10/05. Illness severity: moderate 3 (10%), marked 13 (43%), severe 14 (47%). Tumor histology: glioblastoma multiforme 8 (27%), anaplastic glioma 10 (33%), low grade glioma 10 (33%), meningioma 1 (3%), CNS lymphoma 1 (3%). Treatment: neurosurgical resection 93%, radiotherapy 87%, chemotherapy 70%. The table shows relationships of nine variables at baseline and 8 and 12 weeks after initiation of modafinil. Adverse events reported by ≥ 4 patients: headache 13 (42%); insomnia 8 (26%); dizziness 7 (23%); dry mouth 7 (23%); depressed consciousness 5 (16%); nausea 4 (13%). **Conclusions:** Results show improvement across cognitive, mood, and fatigue outcome measures. Modafinil was generally well tolerated, with a low incidence of adverse events. Greatest improvements in outcomes were observed 8 wks after baseline.

Neurobehavioral and Fatigue Outcome Measures

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Variable	Baseline Mean (SD)	+8 Weeks Mean (SD)	p value	+12 Weeks Mean (SD)	p value
TM-A	35.5 seconds (16.0)	29.7 seconds (21.7)	.01	28.8 seconds (16.3)	.002
TM-B	95.5 seconds (47.2)	68.0 seconds (36.5)	<.0001	73.6 seconds (45.0)	<.0001
SDM-Oral	50.4 (15.3)	61.5 (22.7)	.0002	58.1 (21.6)	.006
SDM-Manual	44.3 (13.3)	54.2 (20.0)	<.0001	50.7 (18.9)	.004
VF	32.5 (15.9)	42.3 (15.6)	<.0001	39.2 (15.3)	.002
HAM-D	17.8 (9.0)	10.4 (6.5)	<.0001	12.8 (8.5)	.007
FSS	5.2 (1.4)	3.6 (1.5)	<.0001	3.5 (1.6)	.0003
MFIS	50.2 (17.0)	30.5 (16.7)	<.0001	28.9 (21.0)	<.0001
VAFS	4.0 (2.4)	6.7 (2.6)	.0001	6.7 (3.0)	.0005

Associated Presentation(s):

1. Pilot study of modafinil for treatment of neurobehavioral dysfunction and fatigue in adult patients with brain tumors.

 Meeting: [2006 ASCO Annual Meeting](#)

 Presenter: [Thomas A Kaleita, PhD](#)

 Session: [Central Nervous System Tumors](#) (Oral Presentation)

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2. Predicting major depression in brain tumor patients.

Psychooncology, England

Vol 11, No 3 (7/12/2002): pp. 230-8

PMID: 12112483 [PubMed - in process]

3. Central nervous system-directed therapy in the treatment of childhood acute lymphoblastic leukemia and studies of neurobehavioral outcome: Children's Cancer Group trials.

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