

ABSTRACT

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Effects of low-dose naltrexone on quality of life in high-grade glioma patients: a placebo-controlled, double-blind randomized trial.

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PURPOSE: At diagnosis and throughout the disease course, patients with high-grade glioma (HGG) experience a diminished quality of life (QOL) and increased fatigue. Naltrexone, an orally semisynthetic opiate antagonist, is FDA-approved for the treatment of heroin/alcohol addiction, and low-dose naltrexone (LDN) has been observed to improve QOL and lower fatigue in other neurological illnesses, such as multiple sclerosis. LDN is believed to function as a partial agonist and can lead to shifts in neurochemicals that reduce fatigue. Based on this, we sought to study whether LDN has an impact on QOL and fatigue in patients with HGG.

METHODS: In a placebo-controlled, double-blind study, we randomized 110 HGG patients to receive placebo (N = 56) or LDN 4.5 mg orally at night (N = 54). Subjects received LDN or placebo at day 1 of concurrent radiation and temozolomide therapy and continued for 16 weeks. Change from baseline in patient-reported outcomes of QOL (Functional Assessment of Cancer Therapy-Brain) and fatigue (Functional Assessment of Chronic Illness Therapy-Fatigue) was assessed.

RESULTS: Demographics were WHO grade IV (85%), male (56%), KPS 90-100 (51%), grossly resected (55%), and mean age of 56 years. QOL and fatigue changes between baseline and post concurrent chemotherapy and radiation therapy were not significantly different between patients receiving LDN or placebo. The adverse event profiles for LDN and placebo were similar and attributed to concomitant use of temozolomide.

CONCLUSIONS: LDN has no effect on QOL and fatigue in HGG patients during concurrent chemotherapy and radiation therapy.

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