News from Good Life

Thank you for entrusting in the compounding services at Good Life Pharmacies to help meet the unique medication needs of your patients. We are excited to share our monthly newsletter with you and look forward to continuing to be your medication problem solvers.

Be sure to visit our new website at **www.goodliferx.com.** You or your patients can contact us via our HIPAA-compliant forms and learn how compounding can provide solutions for your medication challenges.

Please don't hesitate to let us know how we can be of further assistance to you and your practice.

Sincerely,
Jim Andreesen, R.Ph.
Angie Svoboda, Pharm.D. FIACP
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Low Dose Naltrexone (LDN)

Naltrexone is a long-acting oral opiate antagonist which is approved for the treatment of alcohol addiction (50mg tablet taken daily). The mechanism of action is complete opiate blockade, which removes the pleasure sensation derived from drinking alcohol (created by endorphins). Low Dose Naltrexone (LDN) in the range of 3-4.5 mg per day has been shown to have the opposite effect - brief opiate receptor blockade with resulting upregulation of endogenous opiate production. Through the work of Bihari and Zagon, it has been determined that the level of the endogenous opiate met-enkephalin is increased by LDN. Met-enkephalin is involved in regulating cell proliferation and can inhibit cancer cell growth in multiple cell lines. Increased met-enkephalin levels created by LDN thus have the potential to inhibit cancer growth in humans. Phase II human trials of met-enkephalin, and published case reports confirmed the potential role of LDN in treating pancreatic and other cancers. Accumulating evidence suggests that LDN 3.0-4.5 mg orally, taken once daily at bedtime supports immune-modulation which may reduce various oncogenic and inflammatory autoimmune processes. Since LDN can upregulate endogenous opioid activity, LDN may promote stress resilience, social bonding, and emotional well-being. Unfortunately, large scale trials are lacking and are unlikely to be funded given the current non-proprietary status of naltrexone.

Oral Health Dent Manag. 2014 Sep;13(3):721-4.
Med Hypotheses. 2009 Mar;72(3):333-7.

Fibromyalgia Pain Reduced by Low-Dose Naltrexone

Fibromyalgia is a chronic pain disorder characterized by diffuse musculoskeletal pain, fatigue, sleep disturbance and cognitive impairment. A significant number of fibromyalgia patients do not respond adequately to the current drugs (pregabalin, milnacipran, duloxetine) approved for fibromyalgia treatment by the Food and Drug Administration (FDA). Thus, there is still a need for adjunctive therapies.

LDN has been found to be a beneficial, highly tolerable, and inexpensive treatment to reduce daily pain in patients with fibromyalgia. In a single-blind, crossover pilot clinical trial at the Division of Pain Management, Stanford University, LDN reduced fibromyalgia symptoms in ten women meeting criteria for fibromyalgia, with a greater than 30% reduction of symptoms over placebo. In addition, laboratory tests showed that mechanical and heat pain thresholds were improved by LDN. Individuals with higher sedimentation rates (indicating general inflammatory processes) had the greatest reduction of symptoms in response to LDN. It is hypothesized that LDN causes transient blockade of opioid receptors centrally resulting in a rebound of endorphin function which may attenuate pain in fibromyalgia. At low doses (4.5 mg), naltrexone may inhibit the activity of microglia and reverse central and peripheral inflammation. Side effects (including insomnia and vivid dreams) were rare, and described as minor and transient.

A placebo-controlled, double-blind trial was sponsored by the American Fibromyalgia Syndrome Association and reported at the American Academy of Pain Medicine's 28th Annual Meeting in February, 2012. In the new trial, Jarred Younger, PhD, and colleagues from Stanford University, Palo Alto, California, evaluated 30 women with fibromyalgia (average age, 43 years), completing 2 weeks of baseline measurements, 12 weeks of LDN treatment (4.5 mg each day), 4 weeks of placebo, and 4 weeks of follow up.

The primary outcome for all patients was reduction of daily pain, reported through patient symptom severity reports via handheld computer. At the end of the trial, patients reported a 43% reduction in pain during the LDN treatment when compared to the placebo treatment. The only major side effects reported more frequently during the LDN phase of treatment were vivid dreams (37% in LDN vs 13% in placebo) and headache (16% in LDN vs 3% in placebo). During both treatment phases, patients reported similar tolerability (89.2 vs 89.4 out of 100). Further study is warranted.

Exp Biol Med (Maywood). 2017 Jan 1:1535370217724791.
Pain Med. 2009 May-Jun; 10(4):663-72.
Pain Med. 2012; 13(2):Abstract 251.

Naltrexone is not commercially available in a 4.5 mg dose, but our pharmacy can compound LDN by prescription.

Multiple Sclerosis

Low-dose naltrexone is a widely used off-label therapeutic prescribed for a variety of immune-related disorders. The mechanism underlying LDN's efficacy for fatigue, Crohn's disease, fibromyalgia, and multiple sclerosis is, in part, intermittent blockade of opioid receptors followed by upregulation of endogenous opioids. Serum [Met5]-enkephalin levels are lower in humans with multiple sclerosis relative to non-multiple sclerosis patients, and LDN has restored their levels.

A retrospective study was conducted on patients at Penn State Hershey Medical Center diagnosed with relapsing-remitting multiple sclerosis between 2006 and 2015. Two cohorts of patients were established based on their multiple sclerosis therapy at the time of their first visit. One group of patients (n=23) was initially prescribed LDN due to symptoms of fatigue or refusal to take an available disease-modifying therapy. The second group of patients (n=31) was treated with glatiramer acetate (Copaxone®) and offered LDN as an adjunct therapy to their disease-modifying therapy.

Patient data from visits occurring 1-50 months post-diagnosis was evaluated in a retrospective manner. Statistical analyses between the groups and for each patient indicated no significant differences in clinical laboratory values, timed walking, or changes in magnetic resonance imaging.

A six month phase II multicenter-pilot trial with LDN was carried out in 40 patients with primary progressive multiple sclerosis (PPMS). The primary end points were safety and tolerability. Secondary outcomes were efficacy on spasticity, pain, fatigue, depression, and quality of life. Clinical and biochemical evaluations were serially performed. Neurological disability progressed in only one patient. Beta-endorphins concentration increased during the trial and a significant reduction of spasticity was measured at the end of the trial.

A single center, double-masked, placebo-controlled, crossover study at the Multiple Sclerosis Center at UCSF evaluated eight weeks of treatment with LDN 4.5 mg nightly on self-reported quality of life in patients with clinically definite multiple sclerosis. 80 patients were enrolled and 60 subjects completed the trial. 10 withdrew before completing the first trial period: 8 for personal reasons, 1 for a non-MS related adverse event and 1 for perceived benefit. LDN was well tolerated and serious adverse events did not occur. LDN was associated with significant improvement on mental health quality of life indices.

Exp Biol Med (Maywood). 2017 Jan 1:1535370217724791.
Mult Scler J Exp Transl Clin. 2016 Sep 29;2:2055217316672242.
Mult Scler. 2008 Sep;14(8):1076-83.

Annals of Neurology, Volume 9999, Issue 999A, Feb 2010

Notes:

We are not suggesting that LDN be used in place of other treatment for cancer, but that it may be a reasonable adjunctive therapy.

Although sleep disturbances are rare, some patients using LDN have reported vivid dreams. To avoid this, therapy can be started with a lower dose (1.5 mg) and increased slowly over two months.

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