A Single Center, Randomized, Placebo-Controlled, Double-Crossover Study of the Effects of Low Dose Naltrexone on Multiple Sclerosis Quality of Life

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Introduction

- Naltrexone is a mu opioid receptor antagonist US FDA approved for treatment of opiate addiction
- More recently naltrexone in low dose was found to enhance the effects of opiate agonists.
- In 1985 Dr. Bernard Bihari found that HIV infected patients had low levels of endogenous endorphins and hypothesized that increasing their levels would be beneficial.
- Dr. Bihari began using a low dose of 4.5 mg naltrexone taken nightly in the treatment of HIV infected patients with the goal of "normalizing" endogenous endorphin levels
- Anecdotal reports suggest that low dose of naltrexone (LDN) might also benefit MS patients
- A small (N=17) open label study in Crohn's disease found that LDN improved active disease as measured by the Crohn's disease activity index

Materials and methods

Randomized, double-blinded, single center, double-crossover, single center, clinical trial

Trial Participants

- Eligible MS patients
- <75 years of age
- Disease activity index
- Able to use and understand all questionnaires during the trial

Inclusion criteria

- No DMT
- GA
- Placebo at night

Exclusion criteria

- Other DMTs
- GA
- Placebo

Randomized, double-blinded, single center, double-crossover study of the effects of low dose naltrexone on Multiple Sclerosis Quality of Life Inventory (MSQOLI)

Results

- Short Form 36: Mental Components
- Placebo at night
- 4.5 mg Naltrexone at night

- Short Form 36: Physical Components
- Placebo at night
- 4.5 mg Naltrexone at night

- Pain Effects Scale
- Placebo at night
- 4.5 mg Naltrexone at night

- Modified Fatigue Impact Scale
- Placebo at night
- 4.5 mg Naltrexone at night

Conclusions

- 8 weeks of treatment with LDN significantly improved quality of life indices for mental health, pain, and self-reported cognitive function of MS patients as measured by the MSQOLI
- An impact on physical quality of life indices including fatigue, bowel and bladder control, sexual satisfaction, and visual function was not observed
- The benefits of LDN were not affected by disease course, age, treatment order, or treatment with either interferon beta or glatiramer acetate
- The only treatment related adverse event reported was vivid dreaming during the first week of the study drug in some patients
- Potential effects of LDN beyond 8 weeks of treatment were not addressed in this study
- Multicenter RCTs of LDN in MS are warranted

Acknowledgments

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For further information

Information on this and related projects at UCSF can be obtained at http://www.ucsf.edu/med

Please visit http://www.ldners.org/ for more information on this patient funded initiative.