Disclaimer

- All patients referred to in this study were under the care of a licensed physician.
- No funding (or resources) from any department, or The University of Arizona, were used.
- Naltrexone is <u>not</u> a controlled substance.
- Only USP grade naltrexone was used in this study.

Low Dose Naltrexone

As a preferential mu opiate receptor antagonist in the treatment of various autoimmune diseases

Nyles Bauer March 9th 2007

Overview

- Naltrexone has been FDA approved since 1984 for the treatment of opiate abuse and overdose.
- A standard dose is 50mg/day, but 300mg doses have been used in clinical studies.
- Typically Naltrexone is relatively free of side effects in dosages lower than 300mg.
- This study used 4.5mg per day (taken before bed), less than 1/10th the typical dose, in an effort to try and avoid substantial blockade of anything but mu receptors.

Theory of Efficacy

- My starting, and current, thesis is that it is not the absolute level of stimulation of the mu or delta opiate receptor that determines immune system competency, but the relative balance of the two (or more).
- By preferentially blocking the mu receptor, I was hoping to return the balance of agonist stimulation to the delta receptor.

PubMed vs. Google

Initial searches of medical databases for peer reviewed publications on the topic of anti-opiates in the treatment of autoimmune disease, prior to the start of this preliminary investigation, revealed that no studies had been done.

However

At a later date, a standard Google search was done, revealing the work of several physicians and patients themselves in this area with very good results, but often they were nothing short of amazing.

Justification for Naltrexone

- Can be orally administered (unlike naloxone).
- Exhibits a relatively long biological half-life.
- Has higher affinity for the mu opiate receptor than other opiate receptor classes.
- Only exhibits pure opiate antagonist behavior.
- Has a long clinical history, with safety clearly demonstrated.
- Very inexpensive. With bulk purchasing, treatment can cost less than 50 cents/day.

Study Overview

- Approximately 10 patients were referred for treatment over the past year.
- All patients had moderate to severe autoimmune disease states.
- Conditions included:
 - Lupus (Systemic Lupus Erythematosus)
 - Rheumatoid Arthritis
 - Multiple Sclerosis
 - Mixed Autoimmune States

Observations

- Due to the low patient numbers, observations could only be generalized.
 - It appears that the response time to treatment was inversely correlated with the duration of illness.
 - Benefits seem to begin as soon as the first week.
 - Within a month, results were generally profound.
 - No side effects were observed.
 - Many standard prescribed medications could be reduced or avoided altogether.

Preliminary Results

100% of participants had substantial improvement of symptoms with no observable side effects do to the treatment itself.

Let me stress, that this does not mean that 100% of the symptoms were controlled. All regained at least some degree of function lost to the disease process itself, some regained nearly all function.

Future work

- Clearly more data is needed, both in number of patients and specific, objective, laboratory results.
- It would be nice to compare the results of naltrexone to a more specific mu opiate antagonist. Various peptides do exist for this, however, at least one mu receptor subtype (III) found on leukocytes was found not to respond to peptide ligands, but did respond to opium and naltrexone.

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