PROTOCOL DEVELOPMENT

ketamine-assisted therapy (KAT) research in tampa, florida

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I HAVE COMPLETED MY initial presentations of the Ketamine Research Protocol to the Research Committee at the Tampa Veteran's Administration (VA). The protocol for the use of Ketamine-Assisted Therapy (KAT) in the treatment of alcoholism received quite a few critiques. I am now changing the protocol to accommodate all requests (most related to improving safety precautions). I will soon present the improved protocol to the Research Committee for final recommendations. Following this, I will submit the protocol to the Institutional Review Boards (IRB) of both the VA Hospital and the University of South Florida (USF) College of Medicine for final approval. I hope to be on the agenda of the October or November meetings of the IRBs.

Seeking approval

Recently, I requested assistance from Parke-Davis, the manufacturer of ketamine. I asked to obtain permission from Parke-Davis to research ketamine under the auspices of its existing Food and Drug Administration (FDA) Investigational New Drug (IND) permit. I was promised that the company would try to work with me after I submitted to them my protocol along with a letter of approval from an IRB. I will also try to obtain my own IND from the FDA, but that may take from several months to a year. As soon as I am able to secure both IRB approval and FDA approval, I will immediately begin using ketamine to treat my patients. I am hopeful that I will complete the approval process within the next several months and will pilot KAT before the New Year. Ketamine-Assisted Therapy is referred to as Ketamine Psychedelic Therapy (KPT) by the Russian researchers. [For an update on the Russian research and citation of previous articles in the MAPS newsletter, see p. 27.]

Replicating results

The protocol is designed to replicate the data from previous studies that show significant clinical improvement of alcoholic patients after treatment with KAT. This pioneering research was done by Evgeny Krupitsky, MD in Russia and was published in the journal "Alcoholism Treatment Quarterly" in 1992 (9:99-105). His controlled study has demonstrated a marked clinical effect of KAT on alcoholism: 69.8% of patients treated with ketamine stayed sober during the year following treatment, while in the control group only 24% remained abstinent. The first number shows a remarkable clinical success. The control group percentage is congruent with the results of treatment of Alcoholism in the United States, where only 20% to 30% of patients remain sober during the first year after completion of anti-alcohol treatment of ANY modality (pharmacotherapy, psychodynamic psychotherapy, 12-step recovery programs, behavioral psychotherapy, in-patient rehabilitation programs, cognitive psychotherapy, etc.). Therefore, it is very important to replicate the results of Dr. Krupitsky's study in the US.

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Study design

My study design is a prospective, single-dose, parallel group clinical trial. All patients will be randomly assigned to one of two treatment groups. Both groups will follow a standard 12-step model treatment program. The only difference between the groups is that subjects in one group will receive a single administration of a 2 mg/kg, IM dose of ketamine. The ketamine treatment will be administered between the 12th and 16th days of therapy in addition to all other components of the routine three week substance abuse treatment program at the Tampa, FL VA Hospital. There will be 90 patients (45 per treatment group), both males and females, 18-60 years old, who identify alcohol as their drug of choice and satisfy the DSM-IV criteria for Alcohol Dependence. The treatment will be done at the VA Hospital, on the in-patient chemical dependence unit. The study will be completed in 12 to 18 months.

As the first study is gathering data and increasing my experience with ketamine treatment, I will initiate a second project to be conducted on an out-patient basis. The second study will be more comprehensive and is designed as a double-blind, controlled, dose-related, multi-group prospective clinical trial. There will be five groups:

1. control (standard four week 12-step model treatment program);
2. placebo (standard anti-alcohol treatment plus single administration of neutral placebo);
3. single administration of ketamine, 0.5 mg/kg, IM (standard treatment in combination with subtherapeutic dose of ketamine);
4. single administration of ketamine, 2 mg/kg, IM (standard treatment in combination with KAT);
5. single administration of Lorazepam, 0.05 mg/kg, IM (standard treatment plus single administration of pharmacoactive placebo).

In this multi-group study there will be 250 patients (50 per treatment group) treated on an outpatient basis in a residential chemical dependence program. Although the second study will require a larger number of patients, it might be completed within 1.5-2 years, as space will not be limited by the size of the in-patient unit.

I will continue to update you about both studies and will share the acquired knowledge with MAPS' subscribers. I also plan to report on changes of consciousness during ketamine sessions. Thank you for your help and support. •