

long as we continue to operate with the highest standards of research and data collection and to follow the guidelines set forth by the FDA and the European Medicines Agency (EMA), it will be the results of the research (and not ideology) that determines whether or not MDMA is approved as a prescription medicine.

MAPS Prepares for New MDMA/PTSD Study with War Veterans

MAPS is preparing a follow-up study to our US pilot study of MDMA-assisted psychotherapy for the treatment of PTSD, conducted under the direction of MAPS-sponsored researchers Michael Mithoefer, MD, and Ann Mithoefer, BSN. This new study will enroll eight US veterans with PTSD from the wars in Iraq or Afghanistan.

There are three purposes for conducting this study. The first purpose is to see if veterans respond any differently than those who suffer PTSD from sexual assault, sexual abuse, or victims of crime. Veterans made up a small minority of subjects in the Mithoefers' previous study (out of 21 subjects, only two were veterans). The EMA has published guidelines for PTSD research that call for studies with homogenous subpopulations of people who suffer from PTSD from different causes. This is to determine if the same therapy can be administered across these subpopulations. It is possible that people with PTSD from different causes will require different therapeutic protocols for MDMA-assisted psychotherapy, or that some subpopulations could be unresponsive to MDMA-assisted psychotherapy. If people with PTSD from different causes are found to respond well to similarly designed protocols, then we can include all of these subpopulations in the larger Phase 3 multi-site studies. If we find that the treatments are different, we will have to take this into consideration when designing the Phase 3 studies.

The second purpose of this new study in veterans will be to gather methodological information about how different doses of MDMA succeed in creating an effective double-blind study. The researchers and subjects in our pilot study were often able to accurately guess when asked whether subjects had received an active dose of MDMA or an inactive placebo. The new study of veterans involves administering doses of 125 mg, 75 mg, or 25 mg (with four of the subjects randomized to receive 125 mg, two to 75 mg and two to 25 mg). We will see if the use of these three doses can be a successful double-blind study. We will also look to see if people who receive the higher doses showed a larger therapeutic effect than people who receive the lower doses.

The third and final purpose of the study is to enroll some subjects previously excluded for risk factors such as hepatitis C and hypertension. There is not strong evidence that MDMA poses greater risks to people with these health conditions, but we excluded these factors from our first pilot study in order to proceed cautiously and please our Institutional Review Board (IRB). The new protocol will involve special pre- and post-screening and monitoring plans to evaluate whether MDMA can be safely administered to people with previously excluded risk factors. If we

can safely enroll these subjects, then recruitment into our Phase 3 studies will be faster since fewer subjects will be excluded for risk factors.

This protocol will be submitted to the FDA in September. After it is submitted and approved by the FDA, it will be submitted to our IRB. We hope to have the first subject enrolled before the end of November 2009.

On March 4, 2009, MAPS' MDMA/PTSD research was featured on military.com, a popular military website (read the full text of this article on the MAPS website: www.maps.org/media). Since then, numerous war veterans who wish to be in the study have contacted us. However, it is not clear whether all of them will pass the screening process and some may no longer be interested in participating by the time the study gets started. If you know, or are yourself, a war veteran suffering from PTSD who would be interested in participating in a study in Charleston, South Carolina, please contact MAPS at: ask-maps@maps.org.

MAPS Podcasts

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12th and Final Patient Enrolled in Swiss MDMA Study

MAPS' Swiss MDMA/PTSD study has enrolled the 12th and final subject. Nine patients have completed the study; the 10th and 11th are currently in the treatment process. We estimate that the final treatments will take place between three and six months from now, depending upon whether the last subject gets placebo or MDMA. If a subject gets a placebo session, they will later have the option to participate in Stage 2, where they will go through the entire treatment process again but will receive the full dose of MDMA. This is called an "open-label" study. In this way, these subjects serve as their own controls, as well as being part of a matched control group.

The Swiss project is our second study of MDMA-assisted psychotherapy for the treatment of PTSD. While the Clinician Administered PTSD Scale (CAPS) scores in the Swiss research have not dropped as dramatically as they had in our US pilot study, a preliminary analysis suggests that we are likely to obtain statistically significant results. The completion of this study will be yet another major accomplishment for MAPS and for our supporters.

The Swiss study differed from our US pilot study in several ways. Instead of using an inactive placebo as we had in the US study, we used a low-dose active placebo of 25 mg of MDMA, followed by a 12.5 mg booster dose. The population in the Swiss study also differed from our US study in that the majority of subjects had PTSD resulting from accidents and natural causes, rather than from sexual or physical assault. The Swiss study is also smaller than our US study, which enrolled 21 subjects.