ongoing human studies with **mde** and other psychoactive drugs in germany

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MDMA (Ecstasy) and related compounds like MDE (Eve), MMDA and MBDB are thought to exert unique psychological effects in humans, differentiating them from the chemically related stimulant amphetamines and phenethylamine psychedelics. Nichols (1986) proposed that the hypothetical new pharmacological class be designated "entactogens." However, it is still controversial whether the entactogens really do constitute a distinct pharmacological entity.

Currently, we are conducting a study which will enable us to directly compare the actions of MDE with the actions of a stimulant amphetamine, a psychedelic and a placebo.

Previous Studies

In order to contribute to the clarification of this question, we performed the first series of placebo-controlled human experiments with MDE in 1990/1991. The study design included assessments of the subjective, neuroendocrine and sleep-EEG effects of MDE in healthy volunteers. We already reported about those studies in a former issue of the MAPS newsletter in 1993. In conclusion, it was impossible to securely position the entactogens within the range of the chemically related stimulants and psychedelics. The entactogenic effects appeared to be only one part of the spectrum of actions of MDE in humans.

Current Study

Currently, we are conducting a second experimental study, which will enable us to directly compare the actions of MDE with the actions of a stimulant amphetamine, a psychedelic and a placebo. It took us about two years to get all approvals needed for this project. We finally started with the experiments in June 1995.

The design of the study is double-blind. Every volunteer participates in two experimental sessions with the same substance, which may be MDE, methamphetamine, psilocybin, or a placebo. We have planned the study (and have obtained permission) for a total of 32 healthy subjects, i.e. eight subjects per substance.

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Assessments made during the experiments include:

- detailed psychopathological assessments
- neuropsychological studies (assessments of aspects of memory and attention)
- electrophysiological studies (startle reflex)
- studies of cerebral metabolism with positron emission tomography (PET)
- studies of the effects of drugs on neuroendocrine secretion
- and studies of pharmacokinetics and drug metabolism.

For the realization of the study we are collaborating with other departments including the Department of Nuclear Medicine in Aachen, the Department of Psychiatry of the University of Heidelberg (M. Spitzer), the Pharmaceutical Department of the University of Tübingen (K.-A. Kovar) and the Department of Psychiatry of UC San Diego (M. Geyer).

We hope that we will be able to complete the experiments by the end of 1996 or Spring 1997 at the latest. •

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