

Results

1. The test drug group showed 2 effective; 6 fair; 4 not effective; and 8 drop-outs.

2. Tenuate group showed 5 effective; 7 fair, 5 not effective; and 3 drop-outs.

3. Placebo group showed 1 effective; 4 fair; 9 not effective; and 6 drop-outs.

Comment and evaluation.—It seems to this reviewer that the selection of patients could have been a little bit better. Test drug not significantly better than placebo.

Conclusion.—Does not support efficacy.

REVIEW OF SUBMISSION DATED JUNE 17, 1969

Investigator.—Raymond L. Lange, M.D., Milwaukee, Wisconsin.

Study design

Nineteen obese patients, with concurrent cardiovascular disorders whose weight was at least 15% above the optional limits defined by the Metropolitan Life Insurance Company. Study was open and all patients were put on a low calorie diet of 1,000 calories a day.

The purpose here is to evaluate the anorexic effects of fenfluramine as well as its effects on the central and autonomic nervous systems in patients with cardiovascular disorders. The duration of the study varied from 5 days to 326 days. Fourteen of the patients took the drug for at least 6 weeks, and 5 patients took it for less than 6 weeks.

Results

Ten of the 19 patients lost 10 or more pounds during the period of treatment. The dose used in these 10 patients was 20 mgs. t.i.d. Nine of the patients lost less than 10 pounds and most of these lost less than 5 pounds during their period of treatment. One of the subjects took 40 mgs. 3 times a day.

Since one patient took 40 mgs. 3 times a day (which is considered the top dose), this study does not adequately reflect the effects of the top dose given in patients with cardiovascular conditions. The drug in this study in the dose used did not cause any adverse cardiovascular effects. Since we have no placebo control here along with the 1,000 calorie diet, these results do not demonstrate efficacy for fenfluramine with respect to anorexia.

SPECIAL STUDIES

Study No. 1001

Investigator.—Herbert L. Fred, M.D., Houston, Texas

Study Objective

To determine the nature and extent of interaction between fenfluramine and methamphetamine administered at different times on the general feeling of well-being, on CNS symptoms, and incidentally, in influencing loss of weight in obese patients. It was double-blind, cross-over, with each subject taking all 4 drug schedules each for 2 weeks. The order of administration was randomized. As it turned out, each subject took fenfluramine for 2 weeks, methamphetamine for 2 weeks, fenfluramine and methamphetamine for 2 weeks, then the placebo for 2 weeks.

Twelve subjects were used and there was no diet restriction.

Results

The dose used was fenfluramine 40 mgs. twice a day, 5 mgs. of methamphetamine, and placebo.

1. 8 out of 11 subjects lost more than 1 pound a week.

2. The placebo group—5 out of 11 subjects lost more than one pound a week during the treatment period.

Blood pressure effects showed the fenfluramine to produce a slight decrease in blood pressure, as well as a decrease in pulse rate. It is noted that the combination consisting of 40 mgs. of fenfluramine and 5 mgs. of methamphetamine given twice a day produced a greater loss of weight than the fenfluramine alone.