

for Fenfluramine. Even though the protocol is not specifically supplied as such, it has been determined that the study was double-blind, randomized, and divided into four groups of subjects and it lasted for five weeks.

Study No. 2016. Investigator Benjamin A. Rosenberg, M.D., F.A.C.P., Brooklyn, New York.

Study Design: Double-Blind, Cross-Over, and Randomized comparing Fenfluramine with Placebo (compared the 20 mg TID vs. 40 mg TID dose of Fenfluramine). Duration of treatment was six weeks.

Results: The Fenfluramine Group, Sub-Group A. (20 mgs TID), 12 completed the study of of fifteen; nine lost weight from 4 to 12 lbs; two had no change. Sub-Group B, Fenfluramine (40 mgs TID); 14 completed the study out of fifteen; weight loss in eleven and weight gain in three with no change in one; amount of weight loss was from 2 to 11 lbs. (six lost less than 5 lbs., and five lost more than 5 lbs.), one gained 13 lbs., and one gained 1 lb. Sub-Group C, (Placebo Group) twenty-six completed the study out of thirty-three; thirteen of whom lost weight (more than 5 lbs.), and thirteen of whom had no change or gained weight.

Comments.—The firm has totalled up the results and arrived at a pounds/week weight loss. It is more accurate to state the number of pounds each subject lost with each of the medications. The firm's figures as they are presented suggest that the Fenfluramine dose of 40 mgs TID (after all the results were apparently pooled into a pounds/week weight loss) is five times more effective than a Placebo. In actual fact 41% lost more than 5 lbs. with test drug and 50% lost more than 5 lbs. with placebo.

Conclusions.—Data not adequate because;

1. A low calorie diet was not used.
2. Number of patients losing more than 5 lbs. on drug was not significantly greater than those taking Placebo.

CLINICAL STUDIES (CONTROLLED)

Study No. 2020:

Investigator: Robert S. Anderson, M.D., Nashville, Tennessee

Study No. 2025

Double-blind, cross-over, randomized; duration, 9 weeks divided into three 3-week treatment periods; number of subjects, 20; diet varied from patient to patient. Some are on a 1500 calorie diet, others are on a 1800 calorie diet, others, a 1200 calorie diet, 1400 calorie diet; all patients seem to be diabetic. Many of them also had hypertension; and again we note the absence of the measurement of the height of each patient. The dose used here was 30 mg of Fenfluramine 3 times a day, and the actual treatment periods were two—one, placebo, and one drug, each period lasting about 32–38 days.

Results

The data have been closely analyzed and it can be seen that out of the 20 subjects studied, all diabetic, there were 4 patients in which it could be said that the fenfluramine produced a significantly greater weight loss than the placebo. The other 16 subjects showed that fenfluramine did not produce any greater weight loss than the placebo, and, in fact, several patients gained weight while on the test drug.

Comment and evaluation.—This study is poorly designed in that we have no height measurement, and no consistently low caloric diet.

Conclusion

1. This is not considered a well-controlled study.
2. It does not support the claims made for this drug since drug did not influence weight loss when compared to the placebo.

Study No. 2025

Investigator: Dorothy R. Hollingsworth, M.D., West Haven, Connecticut

Study Design:

Thirty-six subjects randomly assigned to one of two treatment groups, fenfluramine, 40 mg. t.i.d. or placebo. Each group was to proceed through two sixty-day treatment periods. All subjects were placed on a 800 calorie diet. Fourteen of the subjects had diabetes and 11 had hypertension.

Study was double-blind.