

Peer Review of Clinical Research on Diatroxal® by Fenestra Research

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The practical goal of supplement testing is to determine whether the supplement actually achieves the intended or claimed results. Clinical research is used to promote new products that benefit consumers and to support the reasoned marketing of dietary supplements to consumers. Research is performed by a rigorous and meticulous means of testing the product to determine the effect of a supplement. The purpose of this review is to determine whether Fenestra Research Labs has produced clinical research on Diatroxal® that supports marketing claims for control of Diabetes symptoms. The results of the Fenestra Research clinical trials for Diatroxal® fully support the product claims of helping to support optimal blood glucose health.

Fenestra Research Labs is an independent research facility that performed objective clinical trials on 100 subjects taking Diatroxal® over a 90-day period. The research reported by Fenestra Research was conducted by a credentialed investigator with experience in the type of research being conducted. Neither the owner of Fenestra Research nor any of its employees have financial ties to Syntratech™, the manufacturer of Diatroxal®, and therefore Fenestra Research provided a non-biased study on Diatroxal® in terms of not having a financial interest in producing a desired outcome. The ingredients of Diatroxal® have no documented, historical, ill-effects on consumers and thus met Fenestra Research's criteria for clinical research.

The study employed 100 subjects ranging in age from 23 to 50 with chronic uncontrolled blood glucose. This was determined by a blood sugar imbalance that must have been presented for a minimum of the last consecutive six months at a frequency of at least 20 times each month, which is an adequate assessment. Subjects were obtained by advertising, which helped insure the recruitment of a random sample of individuals. The stringent inclusion and exclusion requirements were appropriate for the study and rigorous enough to prevent study bias. Furthermore, interviewer bias (where an investigator conducts interviews that are influenced by his or her subjective judgments) was prevented by using objective guidelines for inclusion and exclusion of subjects. These guidelines prevented selection of people who have an underlying condition that might be worsened by the research and may cause those subjects harm. To further protect the subjects, all were required to give their informed consent; via a signature, to participate in the study

The subjects included 47 men and 53 women and were drawn from a large population of people. The subjects were very heterogeneous, represented by

four different races (33 Black, 32 Caucasian, 25 Asian, and 10 Hispanic). Therefore, there was no subject selection bias by race that might have influenced the results. The positive results that were obtained for Diatroxal® from this diverse population that was equally balanced in number of males and females indicates that Diatroxal® will provide similar results in a wide range of individuals who might use the product.

The study by Fenestra Research was a randomized, double blind, placebo-controlled study. Randomized, placebo-controlled, blinded trials are those that typically determine if a new drug will make it into the marketplace and are generally reported in scientific literature. This type of study is a Gold-Standard trial in pharmaceutical testing. All Gold-Standard trials include: randomization, placebo-controlled, blinding, physician oversight and bi-weekly status reports. Fenestra Research met all of these requirements for the Diatroxal® study.

The 100 subjects were equally divided into those who received Diatroxal® and those who received placebo. They were properly randomized into each group. Using this method, a group with similar characteristics is selected and randomly assigned to receive a placebo or to receive the supplement being tested. This serves to remove the possibility of psychological factors affecting the results because the subjects do not know whether they are getting the placebo or the supplement.

Dosing instructions were provided by the manufacturer and the duration of study was 90 days, which is long enough to reliably gauge whether a product related to these changes has a true effect. To protect the subjects, they were instructed to contact their regular healthcare professional if they had any unusual or uncomfortable symptoms during the course of this study. All subjects in the study were instructed to make no changes to their daily consumption of food or liquid relating to the amount, volume, or type consumed, which eliminated diet as a confounding variable. A confounding variable is a variable that may influence study outcomes but may not have been acknowledged or accounted for in original research. Statistically insignificant changes in the placebo group from baseline to 90-day in nearly all Diabetes markers tested confirm the absence of confounding variables.

Standard measurements were taken at time 0, one week later to establish a baseline, followed at 14 day, 30 day, 60 day, and 90 day time points. These time points are adequate to follow the progress of how the supplement is working. The tests were run in triplicate and averaged for the report, which reduces chances for error.

Compliance to the protocol was monitored and maintained through bi-weekly phone calls with Fenestra Labs personnel as well as in-person office visits that carefully followed the subjects during the course of the trial to ensure their health and safety. This is an important component of a clinical trial. There were no dropouts during the study and no adverse effects, both of which are desirable in clinical trials.

The study measured multiple outcomes, which is necessary to determine the overall effects of a dietary supplement. In the Fenestra Research report reviewed here, the measurements that are markers for Diabetes are reported and discussed. These include glycated hemoglobin (A1C), fasting blood glucose (FBG), triglycerides, high and low density lipoproteins (HDL and LDL), cholesterol, and weight loss.

The A1C test evaluates the average amount of glucose in the blood over the last 2 to 3 months. It can help a patient and their healthcare professional to know if the measures they are taking to control the patient's blood sugar balance are effective. It does this by measuring the concentration of glycated hemoglobin.

Fasting blood glucose is another standard measurement to evaluate diabetes. The results of both the A1C and FBG for Diatroxal® reported by Fenestra Research were statistically significant. The A1C dropped from an average of 7.70% to an average of 4.66%, whereas in the control group A1c levels increased .26%. The average drop was 3.04%, with all of the subjects exhibiting A1C levels less than or equal to 5%. In 32% of the subjects, A1C dropped below 4.5%. In contrast, the seven leading pharmaceutical drugs for Diabetes exhibit less than a 1% decrease in A1C and none of these drugs reduce A1C below 7%. Therefore, Diatroxal® produced more than a three-fold decrease in A1C than that produced by pharmaceutical Diabetes drugs. Since none of the ingredients have a history of harmful effects, Diatroxal® most likely does not produce any side effects, in contrast to pharmaceuticals.

Equally dramatic is the change in FBG-it dropped an average of 107.2 mg/dl, compared to an increase in the control group of 8.3 mg/dl. This is quite significant. In comparison, the most that FBG dropped in the top selling diabetes drugs was 36.6 mg/dl. This degree of effect has not previously been reported in medical journals. Diatroxal® produced a three-fold greater reduction when compared to the leading selling pharmaceutical drugs.

Two other factors involved in Diabetes, weight and blood pressure, were also reduced by Diatroxal®, when compared to controls. The average weight dropped by 9.3 pounds, compared to no change in the control group. The systolic blood pressure dropped an average of 28.4, compared to no change in controls. Both of these measurements are statistically significant.

The most life-threatening consequences of diabetes are heart disease and stroke, which strike people with diabetes more than twice as often as they do others. Most of the cardiovascular complications related to diabetes have to do with the way the heart pumps blood through the body. Diabetes can change the chemical makeup of some of the substances found in the blood and this can cause blood vessels to narrow or to block completely. This is called atherosclerosis, or hardening of the arteries, and diabetes seems to accelerate it. Blood lipids such as cholesterol, triglycerides and low and high density lipoproteins are measured to assess cardiovascular risk factors.

Interestingly, blood lipids in both Diatroxal® and placebo groups fell. The drop in blood lipids in the control group is anomalous. However, the Diatroxal®-treated group had a larger decrease in blood lipids than controls, which is beneficial.

There did not appear to be any systematic bias in the Diatroxal® study by Fenestra Research. Systemic bias occurs when the study is flawed in its overall procedure thereby resulting in a study that does not actually measure the desired factors. This is prevented by expert study design and implementation, which was performed by Fenestra Research. Additionally, there were no observed confounding variables in the study. In a study where it appears that there are positive results due to the product studied, confounding variables can contaminate the study findings because they bring up another potential cause for the positive results instead of the product being tested.

In conclusion, the clinical trial performed by Fenestra Research met the criteria for the Gold Standard trial, which is the most rigorous standard to meet. Furthermore, Diatroxal® produced astounding results and outperformed the leading selling pharmaceuticals.