CALOTREN CLINICAL STUDY

Study Context: Testimonials and other small studies suggest that the supplement Calotren may induce weight loss and improve overall well-being. Calotren is primarily composed of collagen hydrolysate (Figure 1). Minimal data on physical and laboratory side effects have been collected. It is hypothesized that the presence of excess yeast in the body may inhibit weight loss and well-being.

Study Objective: To determine if ingesting three months of the supplement Calotren is efficacious for weight loss. To determine if there were any laboratory or subjective side effects of taking Calotren or if there were any other benefits.

Study Design and Setting: Double-blinded placebo-controlled initially for 30 subjects. At the conclusion, there were 9 in the double-blinded portion. There were 8 single-blinded subjects due to manufacturing problems with the liquid placebo. There were 16 drop outs [for various reasons including inability to fast the full three hours prior to sleep or to keep follow-up appointments, subjects moving out of town and subjects lost to follow-up].

Intervention: Daily dose of four Calotren capsules or one tablespoon of Liquid for 3 months Calotren or matching placebo capsule.

There were 33 adult subjects ages 30-61 years recruited from a private rural clinic in Bastrop, Texas. See Table 1 for subject characteristics. Subjects were excluded if they had started any new supplement, herbal preparation, or medication within the last 31 days. They signed an informed consent prior to participation. Subjects were asked to record symptoms weekly or any changes using rating scales or direct comments (Table 2). Prior to initiation of the study, each subject received a physical exam with vital signs and a BMI (body mass index); a baseline lab draw [CMP (complete metabolic profile), CBC (complete blood count), TSH (thyroid stimulating hormone), FLP (fasting lipid profile)]; a UA (urine analysis) by dipstick; a UBHCG (urine beta human chorionic gonadotropin) pregnancy test (only in those females with reproductive potential); an EKG; and a measurement of body fat percent via the Omron Body Fat Analyzer. Additionally subjects were asked to record body measurements (Figure 3) and baseline alcohol and caffeine intake, and a variety of other symptoms (Table 3). Each month all of the above measurements were repeated except the EKG, percent body fat, and the FLP. These were only redone at the end of the study. Each month the subjects were queried about any positive answers and all other systems (figure 4). The *spit test* for the presence of excess yeast in the body was conducted prior to study start. If positive, then the subjects were pretreated with Probiotic. If after completion of therapy the spit test remained positive, the subject commenced the study anyway and continued on the probiotic. In two cases, the subjects elected to restart the Probiotic and continued both the Probiotic and the Calotren to the end of the study. Subjects were instructed to take the Calotren just prior to sleep after a minimum of a three-hour fast.

They were separated into 5 groups: A, B, C, AA capsules, and Liquid. Group B was the placebo. None of the liquid Calotren was placebo. However, the subjects were told that the liquid might be a placebo.

Main Outcome Measures: Primary outcomes included weight lost, inches lost, and laboratory variations. Secondary outcomes included a decrease in BMI, body fat lost, and results of subjective surveys.

Results: Combined Placebo and Calotren: 17 subjects completed the study. 3 were in the placebo group, 14 in the Calotren group. 100% of those completing the study experienced at least some benefit of the Calotren. 59% lost between ½-13 pounds. 81% lost between ½-41 inches. 50% decreased body fat by 0.2-2.4%. 41% decreased BMI. Total Cholesterol decreased 62% and LDL's decreased in 57%. HDL increased in 57%. Triglycerides reduced in 36%. Blood sugars improved in 27%. 76.5% did not show any significant changes in the EKG. The CMP, TSH, UBHCG did not show any significant abnormalities. Of the UAs 64% had minor abnormalities. 12% showed minor CBC changes.

Results: Capsules, Liquid, and Placebo Compared:

Group	Lost Weight	Lost Inches
A (GA):	**100%**	67%
B (PG - Placebo Group):	0%	100%
C (GC):	67%	**100%**
Liquid (LG):	**75%**	**71%**
True Calotren takers (TCTs):	**71%**	**75%**

(TCTs=GA+GC+LG)

67% in the capsule group (CG=GA+GC) lost weight. 75% of the LG lost weight, while none of those in the PG did. 100% of the PG gained 0.75-4lbs. 71% of TCTs lost between ½-13 pounds vs 0% of the PG; 29% of TCT's gained 2.1-9.5 lbs. 81% of TCTs lost between ½-41 inches vs. 100% lost between 0.5-28.5 inches in the PG; 50% of TCTs decreased body fat by 0.4-2.4% vs 50% decreased by 0.2% in the PG; 41% of TCTs decreased BMI by 0.5-1.5 vs 0% in the PG; 55% of TCTs diminished total cholesterol by 2-41 mg/dl vs 67% decreased by 20-29 mg/dl in the PG; 55% of TCTs reduced LDL's by 8-52mg/dl vs 67% diminished by 20-34 mg/dl in the PG; 73% of the TCTs increased HDL by 2-6 vs 0% in the PG; triglycerides reduced in 45% of TCTs vs 0% in the PG; blood sugars improved in 20% of the TCTs vs 33% in the PG; 67% of TCTs did not show any significant negative changes in the EKG or actually improved vs. 67% showed no significant change, but none showed an improvement; the CMP, TSH, and the UBHCG did not show any significant abnormalities in either group; 50% of the UAs in the TCTs were within normal limits (WNL) vs 33% in the PG; there was one allergic reaction in the TCTs vs none in the PG; there were no life-threatening abnormalities in either group. See Figures 5-6 for graphical demonstration of the above results.

Discussion:

Of the ten main parameters measured, the most significant observations were noted in weight, BMI, TGs, and HDL. Two thirds of those taking the capsules lost weight, while three quarters of those on the liquid did also; but none of those on the placebo lost any weight. The decrease in the BMI for 17% of the capsule group, for 75% of the liquid group, and none in the placebo group points to a significant weight loss in the aforementioned groups.

The lab values that significantly showed an improvement over the placebo were TGs and HDL. The fact that none of those in the PG improved TGs, HDL, BMI, or body fat loss lends strength to the results despite the small numbers of the study.

Few side effects of Calotren were detected in this three-month study. There were no laboratory or clinical life-threatening abnormalities. There appears to be minimal effect on blood pressure & pulse rate. The most common adverse reaction was an aversion to the liquid's taste. The remaining adverse effects were unlikely caused by taking Calotren.