STUDY TITLE: EFFECT OF DIABETAINC ON HEMOGLOBIN A1C AND BLOOD LIPIDS IN METFORMIN PATIENTS

A SUMMARY REPORT OCTOBER 18, 2014

A total of 52 diabetic patients ranging from 14 to 69 years of age participated in the study to evaluate the anti-diabetic effects of Diabetain-C. Although the majority of participants were women their subject characteristics namely age, lipid profile and blood pressure or HbA1c levels was not statistically different between the genders, except that the women participants were generally heavier than men.

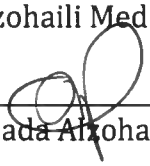
Whilst the subjects on placebo mostly (52.2%) showed increased A1c, all subjects on Diabetain-C showed reduced HbA1c levels except that one patient (#45) on Diabetain-C was found to have increased HbA1c from 6.5 to 6.8%.

There were no significant changes of blood lipids in the treatment group with the exception that the HDL level was slightly reduced in the placebo group.

Patients were given either placebo or Diabetain-C for 90 days. The average HbA1c at baseline was about 7.0% for both treatment and placebo groups, indicating a valid randomization in terms of A1c. Data presented include all of the 52 subjects who participated in the study and all non-missing measurements (N=48) were included in statistical analysis. After treatment the HbA1c increased from baseline by 7.1% in the placebo group and decreased from baseline by 8.5% (HbA1c 0.6) in the treatment group ($p<0.05$). The result after treatment showed that subjects who were on Diabetain-C had 1.1 units less HbA1c than the patients in the placebo group ($p<0.005$). This is equivalent to a reduction of HbA1c by 14.7%.

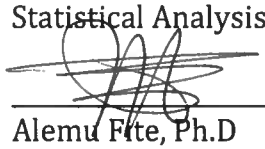
Study conducted by:

Alzohaili Medical Consultants



Opada Alzohaili, MD

Statistical Analysis by:



Alemu Fite, Ph.D

THE EVALUATION OF DIABETAINC DOSE LEVEL AND SAFETY

A SUMMARY REPORT OCT 8, 2013

A total of 30 type 2 diabetes patients ranging from 29 to 72 years of age participated in the study to evaluate dose level and safety.

A patient consent form was signed after a line by line explanation. Subject that require insulin to control his/ her glucose levels and subjects that have diagnosed with type 2 diabetes for longer than ten years were excluded. Patients on blood thinner, antidepressants were also excluded.

The study was conducted by Nutrition Emphasis Center, a diabetes clinic with samples supplied by Omni One, LLC. Patients participated in this study for 6 months.

According to the data provided, DiabetainC was well-tolerated across the board and no adverse reaction was detected. It is determine that DiabetainC is safe to taken and associates with no long-term side-effects. The subsequent study for DiabetainC would be to evaluate the effect of DiabetainC on hemoglobin A1c in metformin patients with a up to 4 capsules per day regimen.

Reported by

Charles H. Liu, Clinical Pharmacist

Alemu Fite, Ph.D, Consultant

STUDY TITLE: EFFECT OF DIABETAINC™ WITH OMNIWAFER™ AS A MEAL REPLACEMENT ON FASTING BLOOD GLUCOSE (FBG), WEIGHT AND BLOOD LIPIDS IN PATIENTS WHO IS ON ANTI-DIABETIC MEDICATIONS IN 30 DAYS

A SUMMARY REPORT October 15, 2015

In this pilot study we investigated Diabetain C nutritional supplement to validate against weight reduction in a total of 9 patients. The study was initiated with a larger number of patients (N=20) who were attending a diabetic clinic. However, clinic personnel misplaced the study supplement so that the study was cut short. Out of the 9 patients who were able to participate in the study 6 completed the course and weight changes were recorded. In addition to weight change patients were interviewed for their energy levels. Changes in energy levels well correlated with the levels of change in weight from baseline.

Table 1. weight reduction following co-administration of DiabetainC and Omiwafer

No	Baseline Wt (lb)	Wt loss (lb)
1	106.2	0
2	88.1	2
3	112	0
4	197.6	7
5	107.4	nd
6	91.3	3.1
7	111.5	nd
8	121.7	nd
9	118.9	2.6
mean	**117**	**2.5**
sd	**32**	**2.6**

In summary the study determined a 67% compliance rate, 67% of whom reported weight loss (mean ±SD: 2.5 ± 2.6 Lb). Equally, 67% of the patients reported increased energy levels in concomitant with weight loss. We have observed that co-administering Diabetain with OmiWafer has a significant effect in weight reduction and increase in energy levels in a significant proportion of participants. An average of over 2% of body weight reduction was observed in this pilot study. The result of this study warrants a larger study and longer follow-up time.

After a power calculation based on this pilot study we have determined the sample size of the main study to be conducted using 26 participants in each arm of control and study groups. In addition, patients will be followed over 3 months and determined for HbA1c analysis before and after intervention. For the main study, participants will be randomly recruited from the same study population in 2016.

Study conducted by

Alzohaili Medical Consultants,
Opada Alzohaili, MD

Analyzed by
Alemu Fite, Ph.D.