

A Placebo-Controlled Double-Blind Pilot Study: Blood Sugar Response to KarboLyn® or a Glucose Drink During Aerobic Activity

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Summary Report

Introduction

All American Pharmaceutical, in Billings Montana, has developed **KarboLyn®** – a homopolysaccharide mixture, for the sole purpose of carbohydrate loading. Across the field of athletics (commercial and amateur) there is a demand for carbohydrate replacers to sustained performance. KarboLyn® was designed for elite athletes looking for a fast and safe way to easily load muscles with accessible muscle glycogen.

This homopolysaccharide is a patent pending process with specific branch-chain structures in the molecular make up. These homopolysaccharides are found naturally in the plant-based food chain. KarboLyn® is considered a nutritional supplement (of plant-based origin) as defined under the Dietary Supplement Health and Education Act (DSHEA) of 1994.

The finished product is a modified molecular mass of homopolysaccharides that is absorbed very quickly without side effects.

Purpose of the study

This Clinical Study sought to document whether or not KarboLyn® has a positive and sustainable impact on blood sugar level during light aerobic activity compared to a simple glucose solution along with evaluating if KarboLyn® was absorbed as quick as a simple sugar. In addition, the company is interested in learning the effect KarboLyn® has on pre-diabetic individuals – whether or not their physiology will show the same glucose utilization curve during sustained, light aerobic exercise.

Experimental protocol

A total of 36 – adults, ages 21 or older, of either gender, were recruited from the Missoula Montana area. All volunteers fulfilled the entrance requirements for their group: ‘Normal’ and ‘Pre-diabetic’. Each individual was randomized to receive either 50 grams of KarboLyn® or an equal gram amount of a sugar drink. Blood was drawn before and during the two hour study, according to the protocol. Volunteers were on a treadmill any time their blood was not being drawn.

Data

At the close of the study the data was reviewed.

KarboLyn® elevated the blood glucose of ‘Normal’ volunteers to a slightly greater extent than the simple glucose drink did at: 15 minute, 30 minute, and 45 minute marks. Approximately 60 minutes after ingestion, and certainly before 75 minutes for all participants, the KarboLyn® blood sugar spike had returned to normal, and in some cases, below the starting value. Blood sugar averages remained between 8 to 14 mg/dl lower than when the participant began.

Glucose placebo

The glucose group showed a spike as well, at the same times that the KarboLyn® did. Between ‘0’ time and 45 minutes, the KarboLyn® spikes were all slightly higher at their respective times. At the 60 and 75 minute marks, the glucose solution gave slightly higher peaks (6 mg/dl and 5 mg/dl, respectively) than the KarboLyn® did.

In general

The normal volunteers exhibited a ‘tighter’ glucose control on ‘spiking’, with most of the reading remaining at, or near, the 100-110 mg/dl mark. Blood glucose usually quickly dipped below 100 mg/dl before the 45 minute mark.

Pre-diabetics

Instead of simply ‘spiking’ their blood glucose level, and fostering a generally high blood glucose level throughout the study, the KarboLyn® **pre-diabetic group** exhibited a very tight ‘spike’ in a bell curve fashion, with almost everyone dropping below 100 mg/dl by the 60 min mark. Before 75 minutes, blood glucoses were below 96 mg/dl. The average blood glucose reading after 75 min – until 120 min (which is the end of the study) was: 81 mg/dl, 78 mg/dl, 79 mg/dl, respectively. This represents a blood glucose that is between 9 – 12 mg/dl lower than their starting glucose levels for KarboLyn® group.

This action was unexpected and has prompted further investigation into the components of KarboLyn® and their potential impact on the pre-diabetic physiology.

SUMMARY:

Normal group

Based on the data so far, KarboLyn appears to get into the blood stream at least as fast as simple glucose, causing a slightly higher ‘spike’ than that produced by glucose, in normal volunteers, during the first 15 – 45 minute, and lasts between 60 – 75 minutes. Since glucose levels were already spiked at 15 minutes, this suggests that KarboLyn® was in the blood stream in about 6-7 minutes.

Simple sugar causes a corresponding spike in normal individuals, but to a slightly lesser degree during the same time frame.

By 75 minutes, both the KarboLyn and the simple glucose are exhausted during light aerobic exercise.

Pre-diabetics

With KarboLyn, the pre-diabetics behaved as if they were ‘Normal’ volunteers. The blood glucose pattern produced was a tight bell-shape curve, ending with all blood glucose levels below the 100 mg/dl mark by 60 minutes. After this point, the line virtually flattened out and remained between 81 mg/dl to 78 mg/dl for the rest of the two hour test. This was unexpected.

With the simple glucose placebo, the blood sugars spiked higher and remained abnormally high longer, before dipping below 100 mg/dl. There was no tight bell curve, rather a ‘peak’ with several ‘slopes’, indicating a poorer glucose control response. Eventually the placebo pre-diabetics did fall into the average 80 mg/dl to 86 mg/dl range by the end of the study.

There were no protocol deviations or adverse events during the study.

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