

Lysulin® – Effective OTC Nutritional Supplement for Type 2 Diabetes

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Introduction

Diabetes mellitus is a leading cause of morbidity and mortality worldwide. Most people with the disease have type-2 diabetes (T2D).

The causes of T2D are multi-factorial, and nutrition plays a key role on its' incidence, severity and management [1].

Recent studies have demonstrated that nutritional supplements containing essential nutrients have beneficial effects in patients with T2D by improving glucose and lipid metabolism, and disease progression.

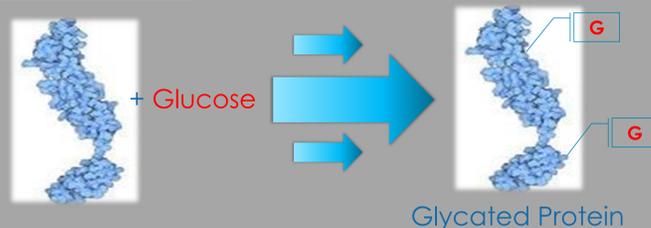
Lysulin® is a patent pending nutritional supplement containing **three essential nutrients**: the amino-acid Lysine, the mineral Zinc and Vitamin C. All three have been shown to lower blood glucose and improve the lipid profile (2).

Lysine is known to react with glucose to form a glycated amino acid that is excreted in urine. This reduces the amount of excess glucose available to react with protein to form glycated protein (See Figure 1).

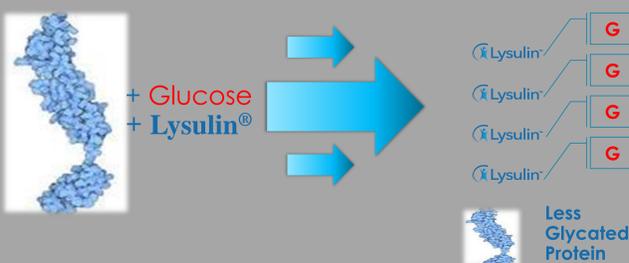
When a protein is glycated, it alters its function. This can lead to complications such as: Retinopathy, Nephropathy, blindness, amputations, kidney failure and other disease complications. [3] Zinc is essential for the formation of insulin in the beta cells of the pancreas. Studies have shown that zinc deficiency is prevalent in people with T2D. [4].

Vitamin C is structurally similar to glucose and can replace it in many chemical reactions and thus is effective for prevention of Glycated Proteins. Previous studies have shown a decrease in vitamin C levels in people with T2D.[5]

Protein Glycation:



Less Protein Glycation in the Presence of Lysulin™



(Figure 1)

Hypothesis

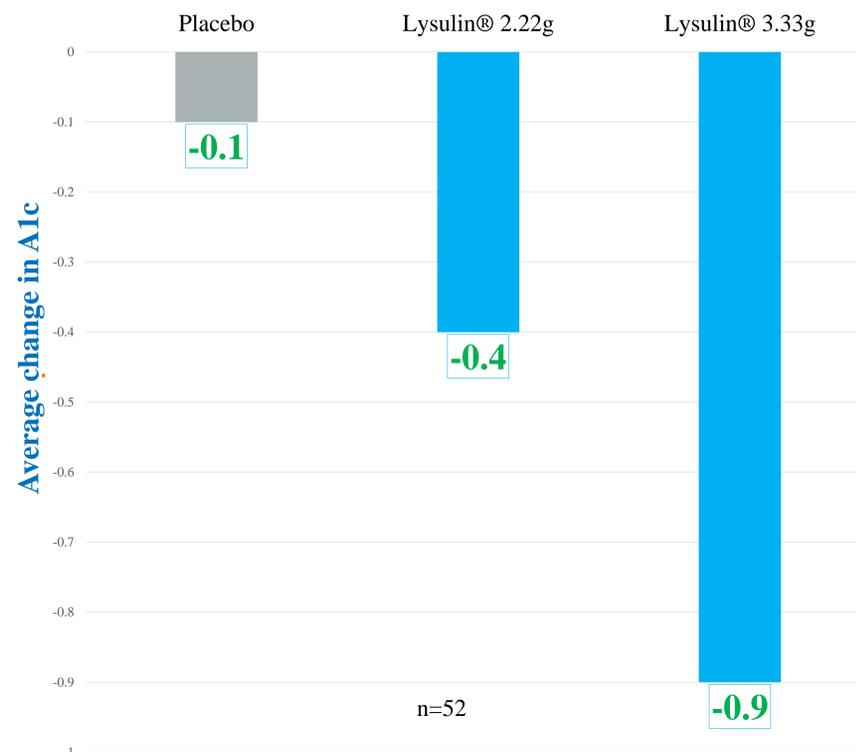
We postulated that Lysulin® containing Lysine, Zinc and Vitamin C will have beneficial effects on glycemic control and disease progression in people with T2D

Methods

1. The present study evaluated this hypothesis using a phase II/III randomized double-blind placebo controlled clinical trial design.
2. A total of 52 participants with T2D with inadequate glycemic control (average 8.2%HbA1c) took part in the study.
3. Participants were randomized into 1 of 3 groups: Placebo, Lysulin® (2.22 g) and Lysulin® (3.33g) and asked to ingest their assigned treatment every day for 12 weeks
4. Clinical and Biometric Lab tests were done at six scheduled visits. All visits included HbA1c measurement. Comprehensive clinical and biometric panel testing were performed at the first and last timepoints.
5. Study test results were analyzed using several statistical techniques from a source database (Excel).

Results

Strong A1c lowering with Lysulin® vs Placebo in 12 Weeks



Changes in A1c test results were observed for some participants in as early as 2 weeks after taking Lysulin®. The following table shows actual participant A1c test results at each time point.

PPT #	Week 0	Week 2	Week 4	Week 6	Week 8	Week 12	Change in A1c	% Change
38	11.2	10.8	11.1	10.4	10.1	10.4	-0.80	-7%
31	10.3	10.1	10	9.4	9.2	9.5	-0.80	-8%
15	7.4	7.0	7.0	7.1	7.3	6.4	-1.00	-14%
48	10.0	9.7	9.6	8.7	8.2	8.5	-1.50	-15%
30	8.7	7.9	7.2	6.7	6.2	6.2	-2.50	-29%
3	8.1	7.4	6.7	6.4	5.9	5.6	-2.50	-33%
10	10.9	9.3	9.3	8.4	7.2	6.9	-4.00	-37%

Conclusions

- There is a strong A1c lowering when Lysulin® (3.33g) is ingested by people with Type 2 Diabetes.
- Changes in the measurement of A1c have been observed in as early as two weeks after taking Lysulin®.
- This study will be continued to Week 26 to see if additional reduction of A1c measurements are achieved with Lysulin®.

References Cited

1. Nutrition Recommendations and Interventions for Diabetes: a position statement of the American Diabetes Association. *Diabetes Care* 2007, 30 Suppl 1:S48-65.
2. Burd, J: Lysulin®, a new supplement for Nutritional Support for People with Diabetes and Pre-diabetes (those at risk of developing diabetes). *Diabetes Manag* (2018) 8(2), 38–40.
3. Kalogeropoulou D, LaFave L, Schweim K, Gannon MC, Nuttall FQ: Lysine ingestion markedly attenuates the glucose response to ingested glucose without a change in insulin response. *The American journal of clinical nutrition* 2009, 90(2):314-320.
4. Kinlaw WB, Levine AS, Morley JE, Silvis SE, McClain CJ: Abnormal zinc metabolism in type II diabetes mellitus. *Am J Med* 1983, 75(2):273-277.
5. Kotb A, Azzam KMA: Effect of Vitamin C on Blood Glucose and Glycosylated Hemoglobin in Type II Diabetes Mellitus. *World Journal of Analytical Chemistry* 2015, 3(1A):6-8.