

Safety test of a supplement, 5-aminolevulinic acid phosphate with sodium ferrous citrate, in diabetic patients treated with oral hypoglycemic agents

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ABSTRACT

Objective: This study aimed to examine the safety of 5-aminolevulinic acid phosphate (5-ALA) with sodium ferrous citrate (SFC) in diabetic patients treated with one or more oral hypoglycemic agents (OHAs).

Background: Recent intervention studies performed in the USA and Japan have shown that a nutritional supplement of 5-ALA with SFC efficiently reduced blood glucose levels in pre-diabetic population without any adverse events. Thus, it was anticipated that 5-ALA with SFC may potentially be taken as a beneficial supplement by diabetic patients who were being treated with OHA therapy. Nevertheless, it is important to examine its safety and efficacy in diabetic population.

Methods: This study was a prospective single-blinded, randomized, placebo-controlled and parallel-group comparison study. Medically treated diabetic patients between the ages of 30 and 75 were recruited from the Tokyo metropolitan area of Japan and 45 subjects were selected after screening. These subjects were randomly assigned to three groups: daily intake of 15mg 5-ALA, 50mg 5-ALA, and a placebo (n=15, respectively). The supplement or placebo was administered for 12 weeks followed by a four week washout period. The primary endpoint was safety and

occurrence of hypoglycemic attack, while the secondary endpoint was changes of fasting blood glucose (FBG) and hemoglobin A1c (HbA1c).

Results: Adverse events related to 5-ALA with SFC were not observed in all the groups. Abnormalities in blood and urine tests were not observed either. Significant decrease in FBG was not detected in all the groups. However, there was a small but significant decrease in HbA1c at 4 and 8 week in the 15 mg 5-ALA group. Significant decrease in HbA1c was not observed in the 50 mg 5-ALA group, although a tendency to decrease after 4 weeks was apparent.

Conclusion: 5-ALA with SFC is a safe and potentially beneficial supplement if taken by diabetic patients treated with OHAs.

Trial registration: UMIN 000008038

Key words: type 2 diabetes, 5-aminolevulinic acid (5-ALA), sodium ferrous citrate (SFC), oral hypoglycemic agent (OHA), hemoglobin A1c (HbA1c), fasting blood glucose (FBG)