

A randomized placebo-controlled trial of alphacalcidol on the preservation of beta cell function in children with recent onset type 1 diabetes

ABSTRACT

Background & aims: This participant-blinded parallel-group randomized placebo-controlled study demonstrated that alphacalcidol (vitamin D analogue) preserves beta cell function in newly diagnosed type 1 diabetes (T1DM) in children. **Methods:** Subjects from outpatient clinic were randomized to intervention and control groups. **Inclusion:** (1) age 8–15, (2) T1DM, (3) duration <8 weeks, (4) no chronic diseases, (5) stable diet. **Exclusion:** (1) vitamin D, calcium supplements or fortified foods, (2) hypercalcemia. **Intervention group** received alphacalcidol 0.25 µg twice daily, while control group received placebo. Insulin given physician-titrated to blood glucose. Safety monitored by serum calcium and phosphate. Beta cell function assessed at 0, 3, 6 months using fasting C-peptide (FCP) and daily insulin dosage per body weight (DID). Primary outcome measured using multivariate repeated measures GLM-ANOVA, with FCP and DID as primary measures and age, gender, sunlight exposure, 25-hydroxy vitamin D, and HbA1c as covariates. **Results:** Of 61 subjects, 7 dropped out. GLM-ANOVA showed that groups were different ($p = 0.019$, Eta-squared = 0.087), with no significant covariates. FCP was higher and DID lower in the intervention group, with males having stronger responses to alphacalcidol ($p = 0.001$). No adverse effects were observed. **Conclusions:** The study confirmed that alphacalcidol can safely preserve beta cell function in newly diagnosed T1DM in children, with a stronger effect in males.

Keyword: C-Peptide; Diabetes mellitus; Type 1; Hydroxycholecalciferols; Insulin-secreting cells; Iran; Randomized controlled trial