Title:

The Effects of Vitamin D Supplementation on Glycemic Control in Children with Type 1 Diabetes Mellitus in Gaza Strip, A Randomized Controlled Trial.

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Running title:

Vitamin D Supplementation and Glycemic Control Improvement among Type 1 Diabetic Children.

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Document Date: November 14, 2021

Statistical analysis

- Statistical Package for the Social Science (SPSS, version 22) was used for data processing and analysis.
- Description of variables was presented as follows:
- Data were normally distributed, as determined using Kolmogorox-Smirnov test.
- Description of quantitative variables were presented as the following: Normally distributed data were expressed as mean ± SD.
- Description of qualitative variables was in the form of numbers (No.) and percent (%).
- Comparison between quantitative variables was carried out by student T-test of two independent samples. Results were expressed in the form of P-values.
- Comparison between qualitative variables was carried out by Chi-Square test (χ^2). Fisher exact test was used instead of Chi- square test when one expected cell or more were ≤ 5.
- Binary correlation was carried out by Spearman correlation test. Results were expressed in the form of correlation coefficient (R) and P-values. The following points are the accepted guidelines for interpreting the correlation coefficient:
    - 0 indicates no linear relationship.
    - +1 indicates a perfect positive linear relationship: as one variable increases in its values, the other variable also increases in its values via an exact linear rule.

Sample size calculation

To calculate the sample size two mean formula was used as follow

$$n = \frac{2\sigma^2}{\Delta^2}\left(z_{\alpha/2} + z_{\beta}\right)^2$$

σ = 67.8 Bilateral large drusen

Δ = 50 (expected improvement in the Bilateral large drusen after intervention

Z (α/2) = 1.96 for α = 0.05 (two-tailed)

z_ (β)= 0.84 for 80% power

$$n = \frac{2(67.8)^2}{(50)^2}(1.96 + 0.84)^2$$

n = 28.8 = 29

Total number of cases = 29 + non response rate 20%

n = 29+ 6= 35 cases in each group