

Effect of the inhibition of a cholesterol membrane transporter on vitamin D absorption: a double-blind randomized placebo-controlled study



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BACKGROUND AND AIM

- Oral supplements are important to prevent and treat vitamin D deficiency
- Despite the growing number of prescriptions, vitamin D's absorptive mechanisms are not clearly elucidated
- By evaluating the effect of ezetimibe on vitamin D absorption, we aim to evaluate if the cholesterol transporter Niemann-Pick C1-Like 1 transporter contributes to it

METHODS

- Design: Randomized, double-blind, placebo-controlled trial
- Sample and setting: 51 medical students, South Brazilian University Hospital
- Intervention: Ezetimibe 10 mg/day or placebo for 5 days (1st -5th)
- Primary outcome: change in 25-hydroxycholecalciferol (25OHD)
- Blood samples 25OHD, parathyroid hormone (PTH), calcium, and albumin on the 5th and 19th days
- After the first blood sample collection, a single oral 50,000 IU cholecalciferol dose was taken by all during a 15g-fat meal
- General linear model adjusted for multiple comparisons by the Bonferroni test. 25OHD by Diasorin Liaison®
- *ClinicalTrials.gov* NCT02234544

RESULTS

- At baseline, 25OHD was < 30 ng/mL and < 20 ng/mL, respectively, in all and in 82.3% of the participants
- 14 days after a single 50,000 IU oral dose of cholecalciferol, mean (SD) changes in serum 25OHD were similar in both groups, after adjustment to baseline 25OHD levels and BMI (p=0.26)
- Mean serum 25OHD, PTH, calcium and albumin levels remained similar in both groups

Figure 1. CONSORT Flow Diagram

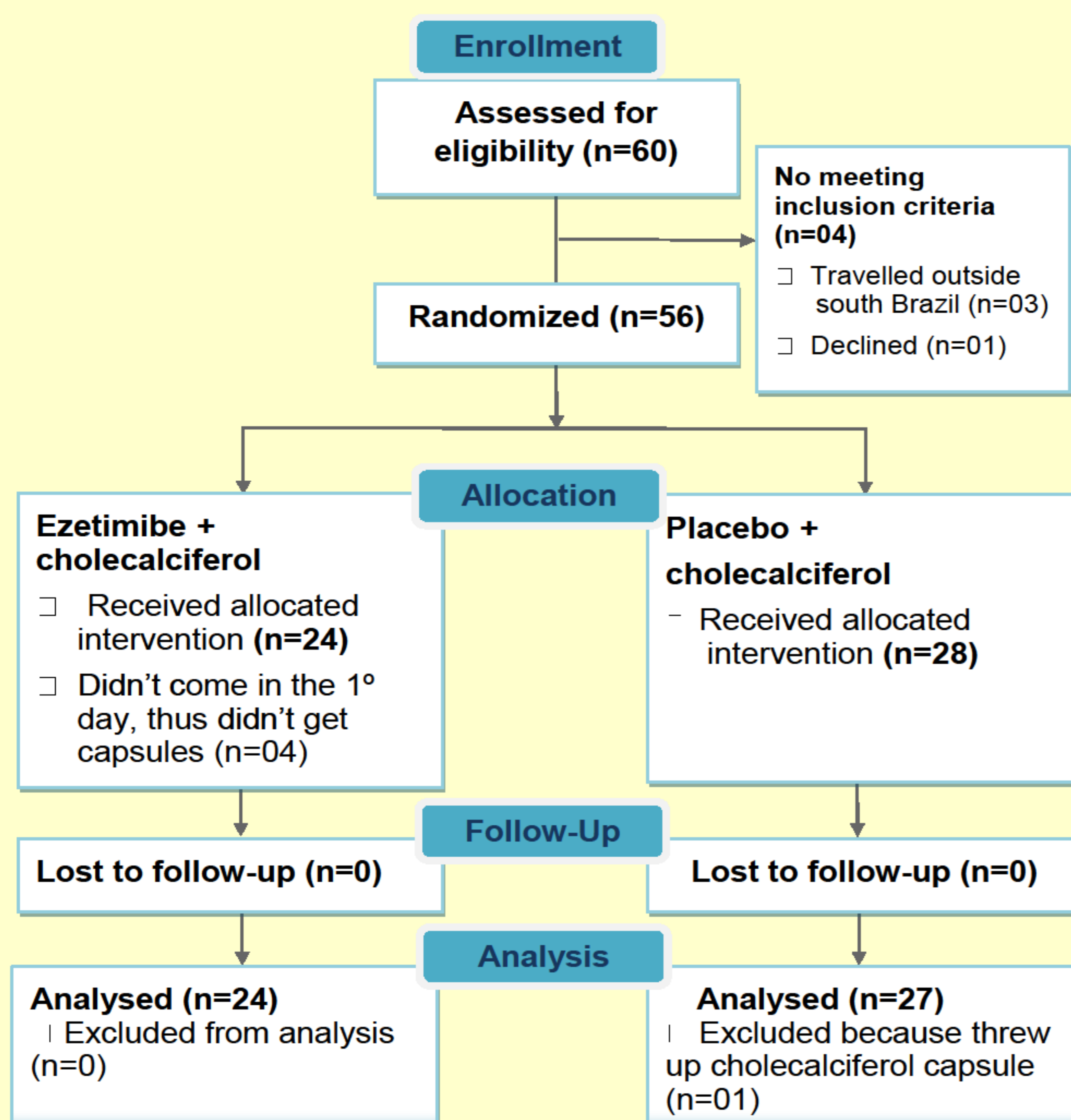


Table 1. Baseline Characteristics of the 51 Participants

Characteristics	Ezetimibe	Placebo
Participants, n	24	27
Male, n	10	11
Female, n	14	16
Age, years	27.82 ± 3.44	27.16 ± 2.73
Weight, kg	65.41 ± 9.30	66.09 ± 10.7
BMI, kg/m ²	22.28 ± 1.75	22.54 ± 1.87
25OHD, ng/mL	15.92 ± 5.63	14.47 ± 4.27
Calcium, mg/dL	9.36 ± 0.44	9.41 ± 0.51
Albumin, g/dL	4.52 ± 0.27	4.58 ± 0.33
PTH, pg/mL	31.35 ± 14.71	33.12 ± 12.80

Table 2. Biochemical responses 14 days after 50,000 IU oral vitamin D3

Measure	Ezetimibe	Placebo	p
25OHD, ng/mL	24.67 ± 5.24	24.49 ± 6.16	0.391
Δ25OHD, ng/mL	8.75 ± 3.74	10.02 ± 3.84	0.26
Calcium, mg/dL	9.32 ± 0.45	9.41 ± 0.39	0.475
Albumin, g/dL	4.51 ± 0.27	4.61 ± 0.33	0.356
PTH, pg/mL	33.51 ± 14.44	34.90 ± 12.85	0.729

CONCLUSIONS

We conclude that ezetimibe had no effect on the mean change in serum 25OHD after a single oral dose of cholecalciferol, in this young adults.

References

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- Reboul, E, et al. *Mol Nutr Food Res.* 2011;55(5):691-702.

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