AUTONOMOUS UNIVERSITY “BENITO JUÁREZ” OF OAXACA (UABJO)

STUDY PROTOCOL:

EFFECT OF VITAMIN D SUPPLEMENTATION ON STENGHT AND MUSCLE GAIN IN OLDER ADULTS WITH OBESITY

NCT: Pending
Document versión: Version 1.0

Principal investigator:
Carlos Valencia Santiago, MSc
l.n.carlosvalencia23@gmail.com
+529511973466
UABJO

Study Site: Instituto Mexicano del Seguro Social (IMSS)
Family Medicine Unit 24
Miahuatlán de Porfirio Diaz, Oaxaca, Mexico

JUNE 2023

STUDY PROTOCOL

Title: Effect of Vitamin D Supplementation on Muscle Strength and Muscle Mass in Older Adults With Obesity in Miahuatlán de Porfirio Díaz, Mexico (2023–2024)

Principal Investigator: M.N.C. Carlos Valencia Santiago Doctoral Program in Biosciences, Faculty of Medicine, UABJO Email: l.n.carlosvalencia23@gmail.com Phone: +52 951 197 3466

Study Site: Mexican Social Security Institute (IMSS) Family Medicine Unit No. 24 (UMF 24) Miahuatlán de Porfirio Díaz, Oaxaca, Mexico

Study Design: Randomized, placebo-controlled, parallel-group clinical trial; single-blind (participants).

Study Dates: Start: November 2023 End of follow-up/data lock: April 2024

Background and Rationale: Obesity in older adults is a growing public health concern in Mexico. The coexistence of excess body fat with reduced muscle mass and strength—known as sarcopenic obesity—is associated with frailty, impaired mobility, increased risk of falls, and decreased quality of life. Vitamin D plays an important role in muscle physiology, influencing protein synthesis, mitochondrial function, and neuromuscular coordination. Older adults often have low serum vitamin D levels due to decreased skin synthesis, limited sunlight exposure, and dietary insufficiency. Although randomized trials have evaluated vitamin D supplementation for muscle function, results remain inconsistent, and evidence in Mexican older adults with obesity is limited. This trial evaluates whether high-dose vitamin D improves muscle strength and muscle mass in this population.

Research Question: What is the effect of daily supplementation with 10,000 IU of vitamin D3 for 12 weeks on muscle strength and muscle mass in older adults with obesity receiving care at IMSS UMF No. 24?

Objectives: Primary objective: To evaluate the effect of daily vitamin D3 10,000 IU for 12 weeks on muscle strength and muscle mass in older adults with obesity.

Secondary objectives: 1) To compare changes in body fat percentage, body adiposity index (BAI), abdominal volume index (AVI), and visceral fat. 2) To assess changes in physical performance using the Short Physical Performance Battery (SPPB). 3) To analyze changes in serum 25-hydroxyvitamin D concentrations.

Study Design and Methods: Interventional clinical trial with two parallel arms. Participants are randomly assigned to a vitamin D group or placebo group. The intervention period is 12 weeks per participant.

Study population: Older adults (≥60 years) with BMI ≥30 kg/m² attending IMSS UMF No. 24.

Inclusion criteria: - Age ≥60 years. - BMI ≥30 kg/m². - Receiving care at IMSS UMF No. 24. - Ability to perform physical tests (handgrip, SPPB). - Ability and willingness to provide written informed consent. - Willingness to take one capsule daily for 12 weeks and attend all visits.

Exclusion criteria: - Hypercalcemia or major calcium metabolism disorders. - Current use of high-dose vitamin D supplements (≥1,000 IU/day). - Use of medications affecting vitamin D metabolism (e.g., anticonvulsants, systemic corticosteroids). - Severe renal or liver disease. - Active cancer or recent chemotherapy. - Major musculoskeletal or neurological impairment preventing testing. - Cognitive impairment limiting understanding or cooperation. - Participation in another clinical trial in the last 3 months. - Any condition considered unsafe by investigators.

Intervention: Vitamin D arm: 10,000 IU vitamin D3 (cholecalciferol) oral capsule once daily for 12 weeks. Placebo arm: visually identical placebo capsule once daily for 12 weeks. Participants are asked to maintain their usual diet and medical treatment.

Assessments: Baseline and week 12: - Anthropometry (weight, height, BMI, waist circumference). - Body composition by bioelectrical impedance (muscle mass, fat mass, visceral fat, metabolic age). - Handgrip strength using a handheld dynamometer. - SPPB score. - Serum 25-hydroxyvitamin D.

Sample Size: Planned sample size: 30 participants (approximately 15 per arm), taking into account expected effect size and 80% power. Final analyzed sample: 29 participants.

Statistical Analysis: Normality will be assessed with the Shapiro–Wilk test. Between-group comparisons will be performed with Mann–Whitney U tests for continuous variables, and chi-square or Fisher's exact test for categorical variables. Within-group changes (baseline vs week 12) will be analyzed with Wilcoxon signed-rank tests. A p-value <0.05 will be considered statistically significant.

Ethics: The study follows the Declaration of Helsinki and applicable Mexican health research regulations. All participants provide written informed consent. Data are coded to preserve confidentiality. Risks are considered minimal and include mild discomfort from blood sampling and rare minor side effects of vitamin D. Participants may withdraw at any time without affecting their medical care.

INFORMED CONSENT FORM

Study Title: Effect of Vitamin D Supplementation on Muscle Strength and Muscle Mass in Older Adults With Obesity in Miahuatlán de Porfirio Díaz, Mexico (2023–2024)

Principal Investigator: M.N.C. Carlos Valencia Santiago Email: l.n.carlosvalencia23@gmail.com Phone: +52 951 197 3466

1. Introduction You are invited to take part in a research study about vitamin D and muscle health in older adults with obesity. Before you decide, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully and ask questions if anything is unclear.

2. Purpose of the Study The purpose of this study is to find out whether taking a vitamin D3 capsule (10,000 IU per day) for 12 weeks can improve muscle strength and muscle mass in older adults with obesity.

3. Study Procedures If you agree to participate: - We will record your age, medical history and routine clinical information. - We will measure your weight, height, waist circumference and body mass index (BMI). - We will measure your body composition (muscle mass, fat mass and visceral fat) using a bioimpedance scale. - We will measure your handgrip strength with a handheld dynamometer. - We will ask you to perform simple physical tests (Short Physical Performance Battery, SPPB). - We will take a blood sample from a vein in your arm to measure vitamin D levels. You will then be randomly assigned to one of two groups: - Vitamin D group: you will take one capsule containing 10,000 IU of vitamin D3 daily for 12 weeks. - Placebo group: you will take one capsule that looks exactly the same but does not contain vitamin D. At the end of 12 weeks, we will repeat the same measurements and blood test.

4. Duration of Participation Your total participation in the study will last about 3 months.

5. Risks and Discomforts The risks are minimal. You may feel brief pain or see a small bruise where the blood is drawn. Vitamin D is generally safe at the doses used in this study, but in rare cases it may cause mild stomach discomfort or headache. If you experience any symptoms that worry you, please contact the investigator or seek medical care.

6. Benefits You may or may not personally benefit from taking part in this study. It is possible that vitamin D could improve your muscle strength or body composition, but this cannot be guaranteed. The information gained may help improve care for other older adults in the future.

7. Confidentiality Your personal information will be kept confidential. Your data will be identified by a code number rather than your name. Any reports or publications will not include information that can identify you.

8. Voluntary Participation and Right to Withdraw Your participation is voluntary. You may choose not to take part or to withdraw from the study at any time without giving a reason.

Your decision will not affect your regular medical care or benefits in any way.

9. Questions or Problems If you have any questions about this study or experience any problems, please contact: M.N.C. Carlos Valencia Santiago Email: l.n.carlosvalencia23@gmail.com Phone: +52 951 197 3466

10. Statement of Consent I have read (or have had read to me) the information above. I have had the opportunity to ask questions and they have been answered to my satisfaction. I voluntarily agree to participate in this study.

Participant Name: _____

Participant Signature: _____ Date: ___ / ___ / _____

Researcher Name: _____

Researcher Signature: _____ Date: ___ / ___ / _____