RESEARCH PAPER

Effect of Calcarea Phosphorica 6X on Serum 25-Hydroxyvitamin D levels and Musculoskeletal Symptoms in Adults with Vitamin D_3 Deficiency: A Double-Blind Randomized Placebo-Controlled Trial

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ABSTRACT

Background

Vitamin D_3 deficiency is frequently associated with musculoskeletal manifestations including muscle pain, weakness, fatigue, cramps, bone and joint discomfort, and impaired physical functioning. Calcarea Phosphorica has traditionally been described in homoeopathic literature in relation to disorders involving bone nutrition, tissue development and musculoskeletal complaints. The present study evaluated the effect of Calcarea Phosphorica 6X in individuals with vitamin D_3 deficiency presenting with musculoskeletal manifestations.

Aim

To assess the effect of Calcarea Phosphorica 6X in mitigating musculoskeletal manifestations in individuals with vitamin D3 deficiency.

Methods

This prospective, unicentric, double-blind, randomized, placebo-controlled clinical trial was conducted at Bharati Vidyapeeth Medical Foundation Homoeopathic Hospital, Pune, including its outpatient, inpatient and rural/urban camp settings. Adults aged 18–45 years with vitamin D_3 deficiency and a Vitamin D Insufficiency Prediction (VDIP) score ≥7 were eligible. Participants received either Calcarea Phosphorica 6X or placebo for 12 weeks. The intervention group received Calcarea Phosphorica 6X 1-1-1, while the placebo group received Saccharum Lactis 1-1-1. Serum 25(OH)D was assessed at baseline and at 12 weeks. Symptomatic improvement was assessed as a percentage based on reduction in the intensity and severity of musculoskeletal symptoms. Statistical analysis was performed using IBM SPSS Statistics version 26.0.

Results

Fifty-four participants were recruited and randomized, of whom two discontinued the study, resulting in 52 participants completing the study and constituting the final analyzed population, with 26 participants in each treatment group. Mean baseline serum 25(OH)D concentration was 18.24 ± 1.43 in the placebo group and 15.59 ± 1.52 in the Calcarea Phosphorica group. At 12 weeks, concentrations were 16.81 ± 1.56 and 28.65 ± 2.38, respectively. The within-group change was −1.43 ± 0.91 in the placebo group and +13.06 ± 1.37 in the Calcarea Phosphorica group; the between-group difference was statistically significant ($p < 0.001$). Mean symptomatic improvement was 13.08 ± 3.51% in the placebo group and 60.00 ± 2.06% in the Calcarea Phosphorica group ($t = -11.54$, $p < 0.001$). Post-treatment vitamin D status also differed significantly between groups ($p < 0.001$).

Conclusion

In this trial, Calcarea Phosphorica 6X was associated with greater improvement in serum 25(OH)D concentrations and reported musculoskeletal symptoms compared with placebo over 12 weeks. Larger, independently replicated and longer-duration randomized trials are required to confirm these findings.

Keywords: Calcarea Phosphorica; vitamin D deficiency; 25-hydroxyvitamin D; musculoskeletal symptoms; homoeopathy; randomized controlled trial; placebo.

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1. INTRODUCTION

Vitamin D is an important component of calcium and phosphorus homeostasis and contributes to skeletal and neuromuscular function. Vitamin D deficiency has been associated with a range of musculoskeletal manifestations, including muscle weakness, generalized pain, bone pain, fatigue, cramps and impaired physical functioning. [6,12-14,31-34,51,54,61]

Serum 25-hydroxyvitamin D [25(OH)D] is widely used for assessment of vitamin D status. Inadequate sun exposure, dietary factors, obesity, skin pigmentation, lifestyle and other environmental factors can contribute to reduced vitamin D availability. [16,17,33,34,45,64]

Musculoskeletal manifestations are clinically important because vitamin D deficiency may present with nonspecific symptoms before overt skeletal disease becomes apparent. Previous literature has examined associations between vitamin D status and muscle function, chronic musculoskeletal pain and skeletal health. [4,12,17,29-31,41,43,51,54,61]

Within homoeopathic literature, Calcarea Phosphorica has traditionally been associated with conditions involving bone development, nutrition, tissue repair and musculoskeletal complaints. [9,10,15,27,63] The present clinical trial was therefore undertaken to evaluate Calcarea Phosphorica 6X in individuals with vitamin D3 deficiency presenting with musculoskeletal manifestations.

The study additionally incorporated a homoeopathic assessment of psoric manifestations. Within the conceptual framework adopted in the study, symptomatic improvement was considered indicative of fulfilment of the psoric objective.

2. AIM

To assess the effect of Calcarea Phosphorica 6X in mitigating musculoskeletal manifestations in individuals with vitamin D3 deficiency.

3. OBJECTIVES

Primary objective:

To assess the effect of Calcarea Phosphorica 6X on serum 25(OH)D levels in individuals with vitamin D3 deficiency.

Secondary objectives:

(1) To assess symptomatic improvement in musculoskeletal manifestations before and after treatment.

(2) To assess the role of psora in deficiency diseases within the homoeopathic framework used in the study.

4. MATERIALS AND METHODS

4.1 Study design and setting

This was a prospective, unicentric, double-blind, randomized, placebo-controlled clinical trial conducted at Bharati Vidyapeeth Medical Foundation Homoeopathic Hospital, Pune, including OPD, IPD and rural/urban camps conducted by the hospital. The planned study duration for each participant was 12 weeks.

4.2 Ethical approval

The study received approval from the Institutional Ethics Committee of Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Hospital, Pune, under Protocol Reference No. BVDUHMC/2024/01, dated 10/07/2024. Written informed consent was obtained from participants before enrolment.

Trial registration: Clinical Trials Registry–India, CTRI/2024/11/076504, registered on 08/11/2024. The first-enrolment date recorded in the registry was an estimated/proposed date; actual recruitment was delayed because the CTRI registration number was received later.

4.3 Participants

Participants aged 18–45 years, of either sex, with vitamin D3 deficiency and fulfilling the study eligibility criteria were considered for inclusion. The VDIP (Vitamin D insufficiency prediction) score was used as a screening tool, with a score ≥7 considered eligible for the present study.

Inclusion criteria

i. Patient attending OPD who falls short of VDIP score will be included for the study.
ii. Age group: 18 years to 45 years.
iii. Patients of both sexes.
iv. Patient irrespective of their community or socio-economic status.
v. Patient who has given the consent for the study.

Exclusion criteria

i. Pregnant and Lactating woman.
ii. Patient already under Vitamin D supplementations.
iii. Patient having chronic illness or are critically ill.
iv. Patient having defined life-threatening pathology.

4.4 Sample size

The thesis calculated the required sample using G*Power version 3.1, assuming $\alpha = 0.05$, power = 0.80, effect size $d = 0.80$, two-tailed testing and an allocation ratio of 1. The calculated requirement was approximately 25 participants per group, and the final planned sample was 26 participants per group, giving a total sample size of 52.

4.5 Randomization and blinding

After confirming participant eligibility and completing baseline assessment, all 54 enrolled participants were randomized using simple coin-toss randomization. Each participant underwent an independent coin toss; heads allocated the participant to the Calcarea Phosphorica 6X intervention arm and tails to the placebo arm. Blinding was maintained using tablets identical in appearance, including size, colour, shape and taste. Participants, investigators, outcome evaluators and statisticians remained unaware of treatment allocation until database finalization and completion of the primary statistical analyses.

4.6 Intervention

The intervention group received Calcarea Phosphorica 6X tablets, administered sublingually at 1-1-1 (one tablet three times daily) for 12 weeks. The placebo group received Saccharum Lactis

placebo at 1-1-1 using the same administration schedule.

All participants received standardized education regarding vitamin D, dietary sources and safe sun exposure. Concomitant vitamin D supplementation was prohibited during the study period. Compliance was monitored through medication logs and tablet counts at follow-up visits.

4.7 Outcome measures

Primary outcome:

change in serum 25(OH)D concentration from baseline to 12 weeks. Serum 25(OH)D was estimated at baseline and after treatment using a standardized chemiluminescence immunoassay at an accredited laboratory.

Vitamin D status was classified as deficient (<20 ng/mL), insufficient (20–29 ng/mL), or sufficient (≥30 ng/mL).

Symptomatic outcome:

musculoskeletal pain, muscle weakness, fatigue, bone and joint discomfort, muscle cramps and stiffness, and difficulty with physical activity were assessed. Symptomatic improvement was expressed as a percentage based on reduction in the intensity and severity of symptoms.

Psoric assessment: psoric manifestations were assessed through homoeopathic case-taking and miasmatic evaluation. Within the homoeopathic conceptual framework used in the study, symptomatic improvement was considered indicative of fulfilment/satisfaction of the psoric objective.

4.8 Follow-up

Participants were scheduled for follow-up at weeks 2, 4, 6, 8, 10 and 12. Follow-up assessments included clinical assessment, symptom evaluation, compliance monitoring and adverse-event documentation. Serum 25(OH)D was reassessed at week 12. No adverse events were reported.

4.9 Statistical analysis

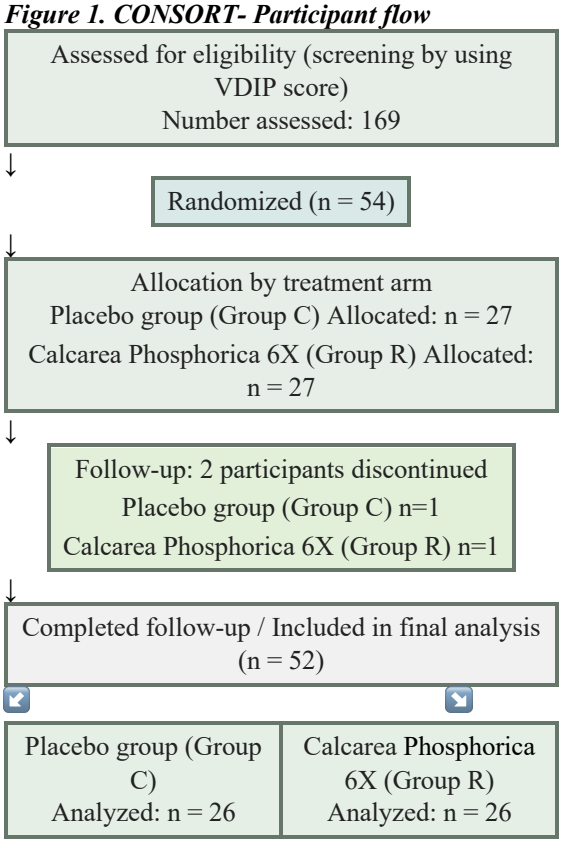
Data were entered and analyzed using IBM SPSS Statistics version 26.0. Continuous variables were summarized as mean ± standard error (SE), while categorical variables were presented as frequencies and percentages. Between-group comparisons of continuous variables were performed using the independent-samples t-test. Within-group pre- and post-treatment vitamin D values were compared using the paired t-test. Categorical variables were analyzed using chi-square or Fisher's exact test where appropriate. The mean change in serum vitamin D concentration and percentage symptomatic improvement was compared between groups using the independent-samples t-test. Statistical tests were two-sided, with $p < 0.05$ considered statistically significant and $p < 0.001$ considered highly significant.

5. RESULTS

5.1 Participant flow

A total of 54 participants were recruited and randomized. Two participants discontinued the study, resulting in 52 participants completing the study and constituting the final analyzed population, with 26 participants in each study arm.

Figure 1. CONSORT- Participant flow



5.2 Baseline characteristics

Characteristic	Placebo Group C (n=26)	Calcarea Phos 6X Group R (n=26)	p value
Age, mean ± SE (years)	26.96 ± 1.10	27.96 ± 1.21	0.545
Female, n (%)	17 (65.38)	19 (73.08)	0.548
Male, n (%)	9 (34.62)	7 (26.92)	

5.3 Serum 25(OH)D

Group	Baseline mean ± SE	12-week mean ± SE	Mean change	t	p
Group C	18.24 ± 1.43	16.81 ± 1.56	−1.43 ± 0.91	−1.54	0.135
Group R	15.59 ± 1.52	28.65 ± 2.38	+13.06 ± 1.37	9.58	<0.001

The between-group comparison of mean change in serum 25(OH)D was statistically highly significant: −1.43 ± 0.91 in Group C versus 13.06 ± 1.37 in Group R ($t = -8.82$, $p < 0.001$).

5.4 Post-treatment vitamin D status

Vitamin D status	Group C	Group R
Deficient	73.08%	19.23%
Insufficient	23.08%	53.85%
Sufficient	3.85%	26.92%

The distribution of post-treatment vitamin D categories differed significantly between groups ($p < 0.001$).

5.5 Symptomatic improvement

Outcome	Group C	Group R	t	p
Symptomatic improvement (%)	13.08 ± 3.51	60.00 ± 2.06	−11.54	<0.001

6.DISCUSSION

6.1 Overview of findings: This double-blind randomized placebo-controlled trial evaluated the effect of Calcarea Phosphorica 6X on serum vitamin D status and musculoskeletal symptoms in individuals with vitamin D deficiency. Participants receiving Calcarea Phosphorica 6X showed a significant rise in vitamin D levels and greater symptomatic relief compared with the placebo group. These findings suggest a beneficial role for Calcarea Phosphorica 6X in improving both biochemical and clinical outcomes associated with vitamin D deficiency [17,46].

6.2 Baseline Comparability: The two study groups were comparable at baseline with respect to age and sex distribution. The absence of statistically significant differences between groups reduces the possibility of confounding and supports the validity of the treatment comparison. The predominance of female participants is consistent with previous reports indicating a higher prevalence of vitamin D deficiency among women [6,14,69].

6.3 Changes in Serum Vitamin D Levels: A highly significant increase in serum vitamin D concentration was observed in the intervention group, whereas the placebo group showed no meaningful improvement. Many participants in the intervention arm shifted from deficient levels to insufficient or sufficient categories after treatment. These findings indicate that Calcarea Phosphorica 6X may positively influence processes related to vitamin D metabolism, utilization, and calcium-phosphate balance. Traditional homoeopathic literature also associates this remedy with bone health, tissue repair, and metabolic regulation [6,14,69].

6.4 Symptomatic Improvement Participants receiving Calcarea Phosphorica 6X experienced substantially greater improvement in musculoskeletal complaints than those receiving placebo. Improvement in vitamin D status may contribute to enhanced muscle function, reduced pain, and better neuromuscular performance. The concurrent improvement in objective laboratory findings and subjective symptoms strengthens the likelihood of a genuine therapeutic effect rather than a placebo response alone [13,30,31].

6.5 Post-Treatment Vitamin D Categories: post-treatment assessment demonstrated a clear shift toward higher vitamin D categories in the intervention group. A considerable proportion of participants achieved insufficient or sufficient vitamin D status, while most placebo-treated participants remained deficient. Since prolonged vitamin D deficiency is linked to osteoporosis, osteomalacia, muscle weakness, and fatigue, these findings have important clinical implications [35,54].

6.6 Possible Mechanisms: The observed effects may be related to improved calcium-phosphate regulation, enhanced utilization of vitamin D metabolites, and support of musculoskeletal function. Additional benefits may arise from improved tissue repair, neuromuscular coordination, and modulation of inflammatory pathways. From a homoeopathic perspective, Calcarea Phosphorica is traditionally used in individuals with nutritional insufficiency, skeletal weakness, and constitutional debility, which may explain its broader therapeutic influence [13,30,31].

7.STRENGTHS OF THE STUDY

The major strengths of this study include its double-blind randomized placebo-controlled design, comparable baseline characteristics, objective measurement of serum vitamin D levels, and complete participant follow-up. The combination of laboratory and symptomatic outcome measures improved the overall reliability of the findings [70,71,72,73].

8.LIMITATIONS

The study was conducted at a single centre with a relatively small sample size and a follow-up period of only 12 weeks. The absence of a standard vitamin D supplementation arm limits direct comparison with conventional treatment. In addition, the biological mechanism underlying the observed effects remains unclear and requires further investigation [6,14,69].

9.CONCLUSION

The findings suggest that Calcarea Phosphorica 6X may serve as a useful complementary approach in

patients with vitamin D deficiency and associated musculoskeletal symptoms. Future multicenter studies with larger sample sizes, longer follow-up periods, and comparison with conventional supplementation are needed to confirm these results. Further research exploring biochemical and molecular mechanisms may help clarify the mode of action of this intervention [6,14,69].

10. DECLARATIONS

10.1 Funding

This study was self-funded by the investigator.

10.2 Conflict of interest

The authors declare no conflict of interest.

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