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Research Article

The Role Of Vitamin D Supplementation In The Prevention Of Acute Respiratory Infections: A Double-Blind Randomized Controlled Trial

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ABSTRACT

Background: Acute respiratory infections (ARIs) remain among the most common causes of morbidity and mortality worldwide, particularly in children, the elderly, and immunocompromised individuals. Emerging evidence suggests that vitamin D, beyond its classical role in calcium–phosphate homeostasis, exerts immunomodulatory effects by enhancing innate immune responses and modulating inflammatory pathways. Previous observational and meta-analytic studies have indicated an inverse relationship between serum 25-hydroxyvitamin D [25(OH)D] levels and susceptibility to respiratory infections. However, inconsistencies persist due to heterogeneity in populations, baseline vitamin D status, and dosage regimens.
Objectives: This study aimed to evaluate whether daily vitamin D supplementation reduces the incidence, duration, and severity of acute respiratory infections compared with placebo among adults with suboptimal baseline 25(OH)D levels. Secondary objectives included assessing changes in serum vitamin D concentrations and evaluating any adverse effects associated with supplementation.
Methods: This double-blind randomized controlled trial was conducted at a tertiary care hospital between January 2023 and March 2024. A total of 400 participants aged 18–65 years with baseline 25(OH)D levels between 10 and 30 ng/mL were randomly assigned into two groups: the intervention group (n = 200) received vitamin D_3 supplementation (2,000 IU daily), and the placebo group (n = 200) received identical capsules without active ingredient, for six months. Incidence of ARIs was documented through monthly follow-up visits and self-reported symptom diaries validated by physician assessment. Primary outcome was the number of ARI episodes per participant over the study period; secondary outcomes included mean duration of illness, symptom severity score, and serum 25(OH)D changes. Statistical analysis employed chi-square and independent t-tests, with significance set at $p < 0.05$.
Results: Of 400 randomized participants, 386 completed the trial (intervention = 193; placebo = 193). Mean baseline 25(OH)D levels were 21.6 ± 5.1 ng/mL in both groups. After six months, the intervention group exhibited a significant rise in mean 25(OH)D levels (to 38.9 ± 6.2 ng/mL; $p < 0.001$) compared with minimal change in the placebo group (22.4 ± 5.3 ng/mL). The incidence of ARI episodes was significantly lower in the vitamin D group (0.68 ± 0.9 per person) versus placebo (1.43 ± 1.2 per person; $p < 0.001$). Additionally, the mean duration of symptoms was shorter (4.1 ± 1.8 days vs. 6.3 ± 2.5 days; $p < 0.001$), and symptom severity scores were reduced. No serious adverse events or cases of hypercalcemia were observed.
Conclusion: Daily supplementation with 2,000 IU of vitamin D_3 significantly reduced both the incidence and duration of acute respiratory infections among adults with suboptimal baseline vitamin D levels, suggesting a protective

immunomodulatory role. These findings support routine assessment and correction of vitamin D deficiency as a feasible public health strategy to mitigate respiratory infection burden, especially in at-risk populations.

Keywords*: Vitamin D supplementation; 25-hydroxyvitamin D; acute respiratory infections; randomized controlled trial; immunomodulation; prevention; adults; public health.*

INTRODUCTION

Acute respiratory infections (ARIs) continue to represent one of the most pervasive public health challenges globally, accounting for substantial morbidity, hospitalization, and mortality across all age groups. According to the World Health Organization, ARIs are responsible for nearly 20% of global deaths in children under five years of age, with a rising burden among adults, particularly those with underlying chronic diseases and compromised immunity. In low- and middle-income countries, frequent viral and bacterial respiratory infections further strain healthcare resources and lead to significant socioeconomic consequences.

Over the past two decades, increasing attention has been directed toward the non-skeletal actions of vitamin D, particularly its immunomodulatory potential in preventing infectious diseases. Vitamin D is a secosteroid hormone synthesized in the skin upon ultraviolet B radiation exposure and obtained from dietary sources or supplements [1]. The active form, 1,25-dihydroxyvitamin D [$1,25(OH)_2D$], interacts with the vitamin D receptor (VDR) expressed on immune cells such as macrophages, dendritic cells, and T lymphocytes. This interaction enhances innate immune defense by inducing antimicrobial peptides like cathelicidin and defensins, which disrupt the membranes of respiratory pathogens. Moreover, vitamin D modulates adaptive immunity by suppressing excessive pro-inflammatory cytokine release, thus reducing tissue damage during infection [2].

Multiple epidemiological and mechanistic studies have demonstrated an association between low serum 25-hydroxyvitamin D [25(OH)D] levels and increased susceptibility to respiratory tract infections [3]. For instance, Martineau et al. (2017) conducted a meta-analysis of 25 randomized controlled trials encompassing over 11,000 participants, which revealed that vitamin D supplementation reduced the risk of ARIs, especially among individuals with severe deficiency (<10 ng/mL) and those receiving daily or weekly dosing. Similarly, other cohort and observational studies have linked seasonal variations in vitamin D levels with peaks in influenza and common cold incidence during winter months, suggesting a possible causal relationship [4].

Nevertheless, despite these promising observations, inconsistencies persist in the literature. Several randomized controlled trials have yielded null or inconclusive findings, often attributed to differences in baseline vitamin D status, supplementation doses, dosing intervals, duration of follow-up, and participant demographics [5]. Furthermore, the optimal serum concentration required for immune protection remains debatable, with thresholds ranging from 20 to 40 ng/mL proposed by various authorities. The clinical relevance of vitamin D supplementation for respiratory health therefore warrants rigorous evaluation through well-designed controlled trials that account for these confounding variables [6].

The biological plausibility of vitamin D's protective role against respiratory infections is supported by its ability to regulate both innate and adaptive immune responses. By enhancing macrophage phagocytic activity and promoting epithelial barrier integrity, vitamin D reduces viral replication and bacterial adherence [7]. Simultaneously, it attenuates the cytokine storm commonly implicated in severe respiratory infections by downregulating IL-6, TNF-α, and IFN-γ while promoting anti-inflammatory IL-10 production. Such dual regulation is of particular importance in conditions like influenza, COVID-19, and community-acquired pneumonia, where exaggerated inflammation contributes to morbidity and mortality.

Given these immunological mechanisms and the persistent global prevalence of vitamin D deficiency, investigating whether daily vitamin D supplementation confers measurable protection against ARIs remains a question of high clinical and public health significance

Therefore, it is of interest to evaluate the efficacy of daily vitamin D supplementation in reducing the incidence, duration, and severity of acute respiratory infections among adults with suboptimal baseline vitamin D levels through a double-blind randomized controlled trial.

MATERIALS AND METHODS

Study Design and Setting

This study was designed as a double-blind, randomized, placebo-controlled trial conducted at the Department of Internal Medicine, a tertiary care teaching hospital in India, between January 2023 and March 2024. The study protocol was approved by the Institutional Ethics Committee and registered with the Clinical Trials Registry of India. Written

informed consent was obtained from all participants before enrolment. The trial was conducted in accordance with the Declaration of Helsinki (2013 revision) and Good Clinical Practice (GCP) guidelines.

Study Population
A total of 400 adult participants aged between 18 and 65 years were enrolled. Recruitment was conducted from hospital outpatient clinics, staff volunteers, and community health outreach programs. Eligible participants were required to have baseline serum 25-hydroxyvitamin D [25(OH)D] concentrations between 10 and 30 ng/mL, indicating insufficiency but not severe deficiency.

Inclusion Criteria
1. Adults aged 18–65 years of either sex.
2. Serum 25(OH)D concentration between 10–30 ng/mL at baseline.
3. No acute respiratory infection in the preceding four weeks.
4. Willingness to provide written informed consent and comply with study procedures.

Exclusion Criteria
1. Known history of hypercalcemia, nephrolithiasis, or renal impairment (eGFR < 60 mL/min/1.73 m^2).
2. Chronic respiratory diseases (e.g., COPD, bronchial asthma requiring systemic steroids).
3. Current or recent use (within 3 months) of vitamin D or calcium supplementation exceeding 800 IU/day.
4. Pregnancy or lactation.
5. Immunosuppressive therapy, autoimmune disease, or malignancy.

Randomization and Blinding
Participants meeting the inclusion criteria were randomized using a computer-generated block randomization sequence (block size = 10) into two equal groups:
- Group A (intervention group): Received vitamin D_3 2,000 IU per day orally.
- Group B (placebo group): Received identical placebo capsules containing inert excipients.

Randomization codes were maintained by an independent statistician not involved in data collection or analysis. Both participants and investigators were blinded to group allocation throughout the study period. Capsules were dispensed monthly in identical opaque blister packs.

Intervention Protocol
The intervention group received vitamin D_3 (cholecalciferol) 2,000 IU daily for six months, while the placebo group received identical capsules devoid of active ingredients. Participants were advised to maintain their usual diet and avoid other vitamin D supplements or fortified products. Adherence was assessed at monthly follow-ups through capsule counts and compliance diaries.

Outcome Measures
The primary outcome was the number of acute respiratory infection (ARI) episodes per participant over six months. ARI was defined as the presence of at least two respiratory symptoms (e.g., cough, sore throat, nasal congestion, dyspnea, or fever ≥38°C) lasting 48 hours or more, confirmed by a physician.

Secondary outcomes included:
1. Duration of illness (days) per ARI episode.
2. Symptom severity scores (on a 10-point visual analogue scale).
3. Changes in serum 25(OH)D concentrations between baseline and six months.
4. Adverse effects, including hypercalcemia or gastrointestinal complaints.

Sample Size Calculation
The sample size was estimated using the formula for comparing two means, assuming a 25% reduction in ARI incidence with vitamin D supplementation, 80% power, 5% alpha error, and a 10% attrition rate. The minimum sample required per group was 180 participants, which was increased to 200 per group (total n = 400) to ensure adequate power.

Data Collection Procedure
Baseline demographic and clinical information, including age, sex, BMI, lifestyle factors (sunlight exposure, diet, smoking), and comorbidities, were recorded using a structured case record form. Participants maintained symptom diaries for ARI episodes, which were validated by study physicians during monthly visits. Serum 25(OH)D and serum calcium were measured using chemiluminescence immunoassay (CLIA) at baseline and after six months.

Statistical Analysis
Data were analyzed using SPSS version 26.0 (IBM Corp, USA). Descriptive statistics were expressed as mean ± standard deviation (SD) or frequencies (%). Between-group comparisons were performed using the independent samples t-test for

continuous variables and the chi-square test for categorical variables. Repeated measures analysis of variance (ANOVA) was used to evaluate longitudinal changes in serum vitamin D levels. A p-value less than 0.05 was considered statistically significant.

Ethical Considerations and Safety Monitoring

All adverse events were recorded and reviewed by an independent Data and Safety Monitoring Board (DSMB). Participants developing hypercalcemia (>10.5 mg/dL) or reporting persistent side effects were withdrawn from the study and appropriately managed.

RESULTS

A total of 400 participants were enrolled in the study and randomized equally into two groups: vitamin D_3 supplementation (n = 200) and placebo (n = 200). Fourteen participants (7 from each group) were lost to follow-up, leaving 386 participants (193 per group) for final analysis. Baseline demographic and clinical characteristics were comparable between groups. The mean baseline serum 25-hydroxyvitamin D [25(OH)D] concentration was 21.6 ± 5.1 ng/mL across all participants. After six months of intervention, the mean serum 25(OH)D level significantly increased in the vitamin D group but remained nearly unchanged in the placebo group. The incidence and duration of acute respiratory infections (ARIs) were significantly lower among participants receiving vitamin D supplementation. No serious adverse events, including hypercalcemia, were observed in either group.

Table 1: Baseline Demographic Characteristics of Study Participants

This table presents demographic data, including age, sex, and BMI, demonstrating comparability between groups at baseline.

Variable	Vitamin D Group (n = 193)	Placebo Group (n = 193)	p-value
Mean Age (years)	39.8 ± 12.1	40.2 ± 11.7	0.74
Male : Female ratio	97 : 96	98 : 95	0.88
Mean BMI (kg/m²)	24.6 ± 3.2	24.8 ± 3.4	0.59
Urban residence (%)	63.7	61.1	0.61

Table 2: Baseline Serum Vitamin D and Calcium Levels

This table shows biochemical baseline levels before intervention initiation.

Parameter	Vitamin D Group	Placebo Group	p-value
25(OH)D (ng/mL)	21.5 ± 5.0	21.7 ± 5.2	0.82
Serum Calcium (mg/dL)	9.3 ± 0.5	9.2 ± 0.4	0.37

Table 3: Change in Serum 25(OH)D Levels After Six Months

This table displays the significant rise in serum vitamin D levels following supplementation.

Timepoint	Vitamin D Group	Placebo Group	p-value
Baseline	21.5 ± 5.0	21.7 ± 5.2	0.82
6 Months	38.9 ± 6.2	22.4 ± 5.3	<0.001

Table 4: Incidence of Acute Respiratory Infections (ARIs)

This table summarizes ARI occurrence per participant.

Outcome	Vitamin D Group	Placebo Group	p-value
Participants with ≥1 ARI episode (%)	29.5	58.5	<0.001
Mean ARI episodes per participant	0.68 ± 0.9	1.43 ± 1.2	<0.001

Table 5: Duration of ARI Episodes (in Days)

This table compares mean illness duration between the two groups.

Variable	Vitamin D Group	Placebo Group	p-value
Mean duration per episode (days)	4.1 ± 1.8	6.3 ± 2.5	<0.001

Table 6: Symptom Severity Scores (0–10 Visual Analogue Scale)

This table demonstrates reduced symptom intensity with supplementation.

Symptom Severity	Vitamin D Group	Placebo Group	p-value
Mean severity score	3.8 ± 1.2	5.9 ± 1.8	<0.001

Table 7: Seasonal Distribution of ARI Episodes

This table outlines ARI occurrence across different seasons.

Season	Vitamin D Group (%)	Placebo Group (%)	p-value
Winter	44.0	61.1	0.008
Summer	27.4	18.6	0.06
Monsoon	28.6	20.3	0.09

Table 8: Compliance with Study Supplementation

This table reports participant adherence to prescribed supplementation.

Compliance Rate	Vitamin D Group (%)	Placebo Group (%)	p-value
≥90% adherence	92.7	91.2	0.64
75–89% adherence	6.2	7.3	—
<75% adherence	1.1	1.5	—

Table 9: Incidence of Adverse Events

This table shows that no major adverse reactions were reported.

Adverse Event	Vitamin D Group (n, %)	Placebo Group (n, %)	p-value
Mild GI discomfort	5 (2.6)	6 (3.1)	0.77
Headache	3 (1.5)	4 (2.1)	0.70
Hypercalcemia	0	0	—

Table 10: Serum Calcium Levels After Six Months

This table confirms biochemical safety regarding calcium metabolism.

Parameter	Vitamin D Group	Placebo Group	p-value
Serum Calcium (mg/dL)	9.4 ± 0.6	9.2 ± 0.5	0.09

Table 11: Subgroup Analysis by Baseline Vitamin D Status

This table compares ARI incidence according to initial 25(OH)D strata.

Baseline 25(OH)D (ng/mL)	Vitamin D Group ARI Episodes (mean ± SD)	Placebo Group ARI Episodes (mean ± SD)	p-value
10–20	0.74 ± 1.0	1.58 ± 1.2	<0.001
21–30	0.61 ± 0.8	1.27 ± 1.1	<0.001

Table 12: Summary of Primary and Secondary Outcomes

This table provides an overall summary of intervention outcomes.

Outcome	Vitamin D Group	Placebo Group	p-value	Effect Size
Mean ARI episodes	0.68 ± 0.9	1.43 ± 1.2	<0.001	0.42
Mean duration (days)	4.1 ± 1.8	6.3 ± 2.5	<0.001	0.56
Mean symptom score	3.8 ± 1.2	5.9 ± 1.8	<0.001	0.48

Table 1 established that both groups were demographically similar, ruling out confounding baseline variability. **Table 2** confirmed equivalence in baseline biochemical parameters, ensuring internal validity. **Table 3** revealed a statistically significant increase in serum 25(OH)D in the intervention group, confirming effective absorption and adherence. **Table 4** demonstrated that vitamin D supplementation significantly reduced ARI incidence, while **Table 5** and **Table 6** highlighted reductions in both illness duration and symptom severity, indicating improved clinical recovery. **Table 7** suggested that protective effects were particularly notable during winter months when baseline vitamin D levels were lowest. **Table 8** reflected high compliance rates across both groups, strengthening data reliability. **Table 9** and **Table 10** confirmed the safety of daily supplementation without biochemical abnormalities. **Table 11** revealed that participants with lower baseline vitamin D benefited most, supporting dose-responsiveness. Finally, **Table 12** consolidated these findings, showing strong statistical significance across all primary and secondary endpoints, thereby reinforcing the preventive efficacy and safety of daily vitamin D_3 supplementation in reducing acute respiratory infection burden.

DISCUSSION

This double-blind randomized controlled trial was conducted to evaluate the efficacy of daily vitamin D_3 supplementation in preventing acute respiratory infections (ARIs) among adults with suboptimal baseline serum 25-hydroxyvitamin D levels [8]. The findings of this study demonstrate a statistically and clinically significant reduction in both the incidence and duration of ARIs in participants who received daily vitamin D supplementation compared to those who received placebo. Moreover, the supplementation regimen was safe and well-tolerated, with no reported cases of hypercalcemia or major adverse effects [9].

The results corroborate and extend the growing body of evidence that implicates vitamin D as a key immunomodulatory factor influencing susceptibility to respiratory infections. The significant rise in mean serum 25(OH)D concentration from approximately 21.5 ng/mL to 38.9 ng/mL among supplemented participants indicates that the dosage of 2,000 IU/day was adequate to restore and maintain sufficient vitamin D status [10]. This biochemical improvement was associated with a 52% reduction in the incidence of ARI episodes and a 35% reduction in mean illness duration, consistent with mechanistic evidence that vitamin D enhances host defense by upregulating antimicrobial peptides and modulating inflammatory cytokine profiles [11].

Several previous trials and meta-analyses have reported similar trends. Martineau et al. (2017) in a pooled analysis of 25 randomized controlled trials involving over 11,000 participants found that vitamin D supplementation reduced the risk of ARI by 12%, with the greatest benefits observed in those with baseline deficiency and in trials employing daily or weekly dosing rather than large intermittent boluses [4]. The current study supports this conclusion by using a daily regimen, which likely provided a more stable serum concentration conducive to immune regulation. Furthermore, the magnitude of protection observed here (about 50% risk reduction) is higher than average meta-analytic estimates, possibly due to the relatively homogeneous baseline deficiency status of the participants and consistent compliance achieved under supervised clinical monitoring [12,13]. The immunological rationale underlying these findings has been well established. Vitamin D receptor (VDR) activation in immune cells stimulates transcription of antimicrobial peptides such as cathelicidin and β-defensin-2, enhancing mucosal defense against respiratory pathogens. Concurrently, vitamin D attenuates the exaggerated pro-inflammatory response often seen in severe viral infections by downregulating interleukin-6 (IL-6) and tumor necrosis factor-alpha (TNF-α) while promoting anti-inflammatory interleukin-10 (IL-10) [14]. This dual role helps maintain epithelial integrity, reduce viral replication, and limit collateral tissue injury mechanisms that together contribute to reduced infection frequency and symptom severity as observed in this trial [15].
In addition, the seasonal distribution analysis demonstrated that the preventive effect of vitamin D supplementation was most pronounced during winter, a period typically associated with lower ultraviolet B exposure and consequently reduced endogenous vitamin D synthesis. This observation reinforces the concept of seasonal susceptibility mediated by vitamin D fluctuations and supports the potential for targeted supplementation during months of reduced sunlight exposure [16]. From a safety perspective, the supplementation dose of 2,000 IU/day proved to be well within the tolerable upper intake level and did not induce hypercalcemia or adverse metabolic effects. Previous safety evaluations have confirmed that daily doses up to 4,000 IU are generally safe for healthy adults, and the current findings further substantiate that moderate-dose continuous supplementation provides effective immune benefits without toxicity risks [17]. The findings also hold significant implications for public health policy. Vitamin D deficiency remains highly prevalent in India and other low-latitude countries despite abundant sunlight, largely due to indoor lifestyles, clothing habits, skin pigmentation, and dietary insufficiency. The observed preventive benefit against ARIs suggests that correcting this deficiency through safe, low-cost supplementation could represent a practical strategy to reduce the overall burden of respiratory illness, lower antibiotic use, and minimize productivity loss due to frequent infections. In addition, during global pandemics such as COVID-19, adequate vitamin D status may serve as an adjunctive protective measure, given its established immunomodulatory effects and the observed associations between low vitamin D levels and adverse respiratory outcomes [18]. Despite these encouraging findings, several limitations must be acknowledged. First, the study population was limited to adults aged 18–65 years without chronic comorbidities, and the results may not be generalizable to pediatric, geriatric, or immunocompromised populations. Second, ARI diagnosis was based on clinical criteria rather than microbiological confirmation, though this approach reflects real-world community practice [19]. Third, while serum 25(OH)D was measured at baseline and at the end of the study, intermediate assessments might have provided greater insight into the temporal relationship between vitamin D levels and infection dynamics. Lastly, the six-month follow-up period may not capture long-term sustainability of the preventive effect [20].

Nevertheless, the study's strengths include its robust randomized double-blind design, large sample size, strict adherence monitoring, standardized outcome definitions, and comprehensive statistical analysis. The use of a daily dosing schedule with a physiologically relevant dose enhances external validity and clinical applicability. Importantly, the trial demonstrated a consistent pattern of benefit across subgroups stratified by baseline vitamin D levels, indicating that individuals with both moderate and mild deficiency may derive measurable advantage from supplementation.

In summary, the present study provides strong evidence that daily oral vitamin D_3 supplementation at 2,000 IU effectively prevents acute respiratory infections, shortens illness duration, and reduces symptom severity in adults with low baseline vitamin D status. The findings emphasize the potential of vitamin D optimization as a simple, safe, and scalable preventive intervention against respiratory infections.

Future research should focus on evaluating long-term benefits, cost-effectiveness analyses, and implementation strategies for population-level supplementation programs. Moreover, trials including high-risk groups such as elderly individuals, healthcare workers, and patients with chronic lung disease could further refine dosage recommendations and optimize preventive strategies for different demographic categories.

CONCLUSION

This double-blind randomized controlled trial demonstrates that daily supplementation with 2,000 IU of vitamin D_3 significantly reduces the incidence, duration, and severity of acute respiratory infections among adults with suboptimal baseline serum 25(OH)D levels. The intervention effectively raised serum vitamin D concentrations without causing adverse effects, underscoring both its efficacy and safety. These results highlight the immunoprotective potential of maintaining adequate vitamin D status and suggest that routine screening and supplementation could serve as a cost-effective preventive measure to mitigate the burden of respiratory infections in the general adult population. Broader implementation of vitamin D supplementation programs, especially during winter months and in populations with high deficiency prevalence, may substantially improve community respiratory health outcomes.

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