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Vitamin D Treatment in ALS: Research Frequency and Clinical Evidence

Overview of Vitamin D Research in ALS

The use of vitamin D as a treatment for amyotrophic lateral sclerosis (ALS) has been investigated in multiple clinical studies, though the research remains limited in scope and scale. While vitamin D supplementation has been explored as a potential therapeutic intervention, the evidence base consists primarily of small observational studies and a single small clinical trial^[1]^[2].

Scale of Research Efforts

Patient Numbers in Clinical Studies

The research on vitamin D treatment in ALS has involved relatively modest patient cohorts across various studies:

- **Individual Study Scale:** Most studies have examined between 37 to 127 ALS patients, with the largest single cohort including 127 patients^[3]^[4]^[5]
- **Systematic Review Coverage:** A comprehensive systematic review analyzed 13 research articles encompassing 1,280 ALS patients across 12 observational studies and one randomized controlled trial^[1]^[2]
- **Treatment Groups:** Specific vitamin D supplementation studies typically involved 20-48 patients receiving active treatment^[6]^[7]^[8]

Research Distribution

The frequency of vitamin D treatment studies in ALS can be characterized as follows:

- **Total Studies:** Approximately 13-15 clinical studies have specifically investigated vitamin D levels or supplementation in ALS patients^[1]^[2]
- **Treatment Studies:** Only 5-6 studies have actually examined the effects of vitamin D supplementation on ALS progression^[1]
- **Controlled Trials:** Just one small randomized controlled trial has been conducted, though it had significant methodological limitations^[1]

Clinical Trial Evidence

Supplementation Studies

Several key studies have examined vitamin D supplementation in ALS patients:

Mount Sinai Study (2013): This retrospective study examined 37 consecutive ALS patients, with 20 patients receiving 2000 IU of vitamin D daily for 9 months^{[6] [8]}. The study found that 81% of patients had vitamin D levels below normal range, and supplementation was associated with slower decline in ALSFRS-R scores at 9 months^[6].

Italian Randomized Trial (2019): A randomized study of 48 ALS patients with low vitamin D levels tested three different dosages (50,000, 75,000, and 100,000 IU monthly) over 6 months^[7]. Despite achieving higher vitamin D blood levels, the study found no significant effects on motor dysfunction progression^[7].

French Cohort Studies: Multiple French research groups have examined vitamin D supplementation, with mixed results showing both potential benefits and null effects^{[1] [3]}.

Prevalence of Vitamin D Deficiency in ALS

Research consistently shows that vitamin D deficiency is common among ALS patients:

- **Deficiency Rates:** 81-82% of ALS patients have been found to have vitamin D levels below normal ranges^{[6] [9]}
- **Severe Deficiency:** 16-43% of ALS patients have severe vitamin D deficiency (levels below 20 ng/mL)^{[6] [9]}
- **Comparison to Controls:** ALS patients have slightly lower vitamin D levels than healthy controls, with a mean difference of approximately 6 ng/mL^{[1] [2]}

Research Limitations and Frequency Constraints

Study Design Issues

The research on vitamin D treatment in ALS faces several limitations that have constrained the frequency and quality of studies:

- **Sample Size:** Most studies involve small patient cohorts, limiting statistical power^{[1] [2]}
- **Methodological Concerns:** Many studies lack proper controls for confounding factors such as reduced sun exposure due to mobility limitations^{[10] [1]}
- **Short Duration:** Treatment studies typically follow patients for 6-9 months, which may be insufficient to detect meaningful clinical changes^{[7] [8]}

Conflicting Results

The limited research has produced mixed findings:

- **Positive Effects:** Two studies showed small improvements in functional decline^{[1] [8]}
- **Negative Effects:** Two studies reported deleterious effects on ALSFRS-R scores^[1]
- **Null Results:** Several studies found no relationship between vitamin D levels and disease progression^{[1] [2]}

Current Clinical Practice

Supplementation Recommendations

Despite limited evidence for disease-modifying effects, vitamin D supplementation is commonly recommended for ALS patients:

- **General Health:** Vitamin D supplementation is advised to prevent complications of deficiency, particularly given the high prevalence of low levels in ALS patients^{[10] [1]}
- **Safety Profile:** Studies have consistently shown that vitamin D supplementation at doses of 2000 IU daily is safe in ALS patients^{[6] [8]}
- **Dosage Monitoring:** Clinical practice typically involves checking vitamin D levels and supplementing based on blood levels rather than for ALS-specific therapeutic effects^[10]

Conclusion

Vitamin D treatment in ALS has been investigated in a limited number of studies involving approximately 1,280 patients across all research efforts^{[1] [2]}. While vitamin D deficiency is highly prevalent among ALS patients, occurring in over 80% of cases^{[6] [9]}, the therapeutic use of vitamin D supplementation specifically for ALS treatment remains investigational. The research frequency has been constrained by small sample sizes, methodological limitations, and conflicting results, with no definitive evidence supporting vitamin D as a disease-modifying therapy for ALS^{[1] [2]}. However, supplementation continues to be recommended for general health maintenance in this patient population^{[10] [1]}.

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1. <https://www.frontiersin.org/journals/neurology/articles/10.3389/fneur.2020.00697/full>
2. <https://pubmed.ncbi.nlm.nih.gov/32849187/>
3. <https://www.frontiersin.org/journals/neurology/articles/10.3389/fneur.2020.00363/full>
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