Is high-dose oral B₁₂ a safe and effective alternative to a B₁₂ injection?

Yes. Both high-dose oral B₁₂ and injected B₁₂ raised low vitamin B₁₂ levels and improved hematologic parameters and neurologic symptoms in short-term studies (3-4 months) predominantly involving patients with conditions associated with intestinal malabsorption (strength of recommendation: A, randomized controlled trials [RCTs]). Both forms are well tolerated. Oral B₁₂ is less expensive.

Evidence summary

Two open-label RCTs compared oral and intramuscular (IM) therapy for vitamin B₁₂ deficiency.¹ ² Both studies enrolled patients from hospital-based clinics—not primary care centers. Most patients (63 of 93 total) had conditions associated with intestinal malabsorption, including 7 patients with pernicious anemia and 3 with ileal resection. Both trials excluded patients with celiac and inflammatory bowel disease.

Oral therapy works as well as injections and costs less

One RCT compared the effects of oral B₁₂ with IM therapy in 60 patients (mean age 62 years) with B₁₂ deficiency and megaloblastic anemia.¹ Investigators gave patients in each group equivalent doses of cobalamin: 1000 mcg daily for 10 days, weekly for 4 weeks, and then monthly to complete a 90-day course.

The mean hemoglobin increased significantly in both the oral and IM groups (from 8.4 to 13.8 g/dL, P < .001 for oral therapy; from 8.3 to 13.7 g/dL, P < .001 for IM therapy), as did mean serum B₁₂ levels (from 73 to 214 pg/mL, P < .001, oral; and from 70 to 226 pg/mL, P < .001, IM). Neurologic symptoms (sensitive peripheral neuropathy, alteration of cognitive function, loss of sense of vibration) either cleared or improved markedly in both groups within one month (7 of 9 patients with oral therapy and 9 of 12 patients with IM treatment; P value not given).

Oral therapy cost less ($80 vs $220 per patient) and neither group reported adverse effects.¹

B₁₂ therapy changes hematologic parameters

The second RCT compared oral with IM B₁₂ therapy in 33 patients (mean age 72 years) with newly diagnosed B₁₂ deficiency.² Investigators randomized patients to receive either oral cyanocobalamin (2000 mcg daily) for 120 days or IM cobalamin (1000 mcg) on Days 1, 3, 7, 10, 14, 21, 30, 60, and 90.

At 4 months, both groups had improved significantly from baseline in all metabolite measures and achieved a normal serum cobalamin level. The higher-dose oral therapy raised cobalamin levels more than IM therapy (from 93 to 1005 pg/mL, P < .0005 with oral therapy vs from 95 to 325 pg/mL, P < .0005 with IM treatment). Oral therapy increased cobalamin levels above 300 pg/mL in all pa-
patients; only half the patients treated with injections reached that level.

B12 therapy also significantly changed hematologic parameters from baseline even though the patients in the study didn’t have anemia. Mean corpuscular volume, for example, decreased from 100 to 90 fl with oral therapy and 102 to 97 fl with IM therapy (P<.005 for each). Neurologic symptoms (memory loss, paresthesias, ataxia) either cleared or improved markedly in all patients. Investigators compared all parameters against baseline values but didn’t directly compare oral with IM therapy. The trial didn’t assess safety outcomes.2

Recommendations
Canada’s British Columbia Medical Association and Ministry of Health recommend oral replacement of B12 (1000-2000 mcg/d) for most cases of vitamin B12 deficiency, including pernicious anemia. For patients with neurologic symptoms, they recommend an initial B12 injection (1000 mcg IM) followed by oral replacement.3

The US Centers for Disease Control and Prevention recommends either oral (1000 mcg daily) or parenteral B12 replacement. They advise giving parenteral therapy either subcutaneously (to reduce the burning sensation) or IM (1000 mcg per week for 8 weeks, then monthly for life).4

References

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