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Conservative regimen supplies necessary vitamin D (as emulsified D3) without the increased risk of hypercalcemia commonly associated with single, large dose therapies.

Effective:

Two drops daily (2,000 IU) increased 25(OH)D concentrations in vitamin D deficient children 202% in six weeks, effectively tripling 25(OH)D levels.*

Easy to Administer for Greater Compliance:

Dispense one drop directly onto the tongue each day.

**Gordon CM, et al. Treatment of hypocitaminosis D in infants and toddlers. J Clin Endocrin Metab. First published ahead of print 4/15/08 as doi: 10.1210/jc.2007-2790*

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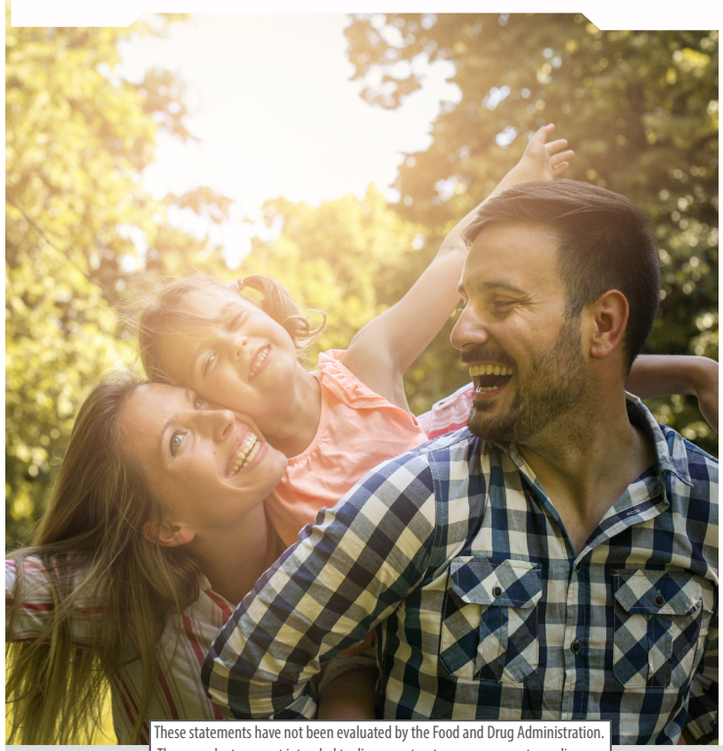

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These products are not intended to diagnose, treat, cure, or prevent any disease.

Ask your healthcare professional which Vitamin D product is right for you.

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LIT-257 Rev. 03/19

Vitamin D

THE SUNSHINE VITAMIN

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What You Need to Know About Vitamin D

What Is Vitamin D?

Vitamin D, commonly called the "sunshine vitamin", is an essential nutrient produced by the body when exposed to sunlight. It is considered a fat-soluble vitamin, but it is, in fact, a "prohormone" produced in the skin from 7-dehydrocholesterol. Prohormones are substances that the body converts into a hormone. Vitamin D is also known as calcitriol, ergocalciferol, calcidiol and cholecalciferol.

Why Is Vitamin D Important?

In addition to vitamin D playing a key role in the regulation of calcium and phosphorous (and, therefore, the development of healthy bones and teeth), vitamin D helps support brain health, metabolism, immunity, optimal weight, heart function including blood pressure regulation, and the maintenance of healthy blood sugar levels. Once known to influence 4 target organs in the body, research shows vitamin D may involve as many as 36 target organs. At the molecular level, vitamin D (1alpha, 25(0H)2D3) plays a significant role in the immune system, the secretion of insulin by the pancreatic cells, the functioning of the heart and blood pressure regulation, multitude of activities of the brain and, also, fetal development. In other words, recent research has shown that vitamin D3's sphere of biological influence is much broader than originally thought.

How Much Vitamin D Do I Need?

Generally speaking, most people require 10-30 minutes of decent exposure to sunlight 3-4 times a week in order to naturally synthesize enough vitamin D. It can also be found in some foods such as oily fish, beef liver, egg yolks, mushrooms and some fortified foods such as milk and breakfast cereal, but only about 10% of what the body needs comes from food. Surprisingly, nearly half of the American population is deficient in vitamin D levels, with serum vitamin D concentrations less than 20 ng/ml (50 nmol/L). Some healthcare practitioners define vitamin D deficiency at much higher parameters, which would mean even more people are deficient.

It is important to speak to your healthcare practitioner about how to get adequate amounts of vitamin D, whether it be from the sun, food and/or supplementation.

What Form of Vitamin D Should I Take?

Vitamin D3 (1α,25(OH)2D3) is the most biologically active form of vitamin D. For better absorption, choose emulsified forms of vitamin D. Because vitamin D is a fat-soluble vitamin, emulsified forms are more bioavailable. Also, look for vitamin D supplements with added vitamin K, which has been shown to support bone and cardiovascular health. However, consult with your healthcare practitioner before taking any supplements as some may be contraindicated in your medical plan.

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With the discovery of vitamin D receptors in tissues other than the gut and bone - particularly the brain, breast, prostate and lymphocytes - recent research suggests the utilization of higher amounts of supplemental vitamin D_3 for a wider range of applications in order to maintain and improve patients' health.

Bio-D-Mulsion® & **Bio-D-Mulsion 1000®** from Biotics Research both supply vitamin D_3 as a micro-emulsion for enhanced absorption and utilization, which is particularly important for those with malabsorption conditions. Clinical use of Biotics' micro-emulsified vitamin D provides significant improvements in serum levels of 25-OH-vitamin D following supplementation.

Bio-D-Mulsion® supplies 400 IU of vitamin D_3 per drop, while **Bio-D-Mulsion 1000®** supplies 1,000 IU of vitamin D_3 per drop.

Safe - Conservative regimen of **Bio-D-Mulsion 1000®** supplies necessary vitamin D (as emulsified D_3) without the increased risk of hypercalcemia, commonly associated with single, large dose therapies — especially important in an outpatient setting.*

Effective - One (1) drop daily of **Bio-D-Mulsion 1000®** (1,000 IU) increased 25(OH)D concentrations in vitamin D deficient children 202% in six weeks, effectively tripling 25(OH)D levels.*

Easy to Administer for Greater Compliance - Simply dispense one (1) drop from the bottle directly onto the tongue each day.*

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The majority of people in the United States do not synthesize sufficient vitamin D in order to meet physiological requirements.

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Bio-D-Mulsion 1000® & Bio-D-Mulsion®

Micro-Emulsified for Greater Uptake and Utilization

While we are all familiar with the importance of vitamin D in calcium absorption and bone metabolism, many may not be aware of the recent research on vitamin D and the widening range of applications available for cholecalciferol, which can be classified as both a vitamin and a pro-hormone.(1) Additionally, while it has commonly been assumed the upper limit of safe intake is approximately 1,000 IU per day, we now know that the physiologic requirement of vitamin D may be as high as 4,000 IU per day, which is less than half of the 10,000 IU that can be produced endogenously with just a few minutes of sun exposure.(2)

Vitamin D Deficiency and Musculoskeletal Health

Vitamin D deficiency is associated with dull, achy musculoskeletal pain that is incompletely responsive to both pharmacologic and manual therapies. The pain may be widespread or confined to a particular area, most commonly the lower back and lumbar spine. The process by which this occurs has been clearly defined: 1) vitamin D deficiency causes a reduction in calcium absorption, 2) production of parathyroid (PTH) hormone is increased to maintain blood calcium levels, 3) increase PTH results in increased urinary excretion of phosphorus, which leads to hypophosphatemia, 4) insufficient calcium phosphate results in deposition of unmineralized collagen matrix on the endosteal (inside) and periosteal (outside) surface of bones, 5) when the collagen matrix hydrates and swells, it causes pressure on the sensory-innervated periosteum resulting in pain.(3) Indeed, several clinical investigations have recently shown vitamin D deficiency is particularly common among people with musculoskeletal pain.(4,5)

Non-Musculoskeletal Manifestations of Hypovitaminosis D

Both the peripheral and central nervous systems have multiple sites of action for vitamin D, and it appears likely that vitamin D modulates serotonin and melatonin synthesis and metabolism. Alterations in vitamin D levels appear to explain, at least in part, the adverse psychological effects of sunlight deprivation that often occur due to geographic location and climate.(6)

Preliminary evidence suggests vitamin D deficiency may also be particularly common among patients with inflammatory and autoimmune disorders, and that vitamin D may modulate inflammatory responses.(7,8,9)

Bio-D-Mulsion® and the Importance of Micro-Emulsification

Biotics Research Corporation's vitamin D is micro-emulsified to enhance absorption and utilization, which are particularly important for those with malabsorption conditions. Independent clinical experience suggests the micro-emulsion form of vitamin D provides significant improvements in serum levels of 25-OH-vitamin D following supplementation.

Each drop of **Bio-D-Mulsion®** supplies 400 IU of vitamin D_3, while each drop of **Bio-D-Mulsion 1000®** supplies 1,000 IU of vitamin D_3. With an increased knowledge of the importance of maintaining adequate vitamin D levels, many clinicians recommend supplementation and annual screening for 25-OH-vitamin D levels, especially for patients at risk for deficiency as well as those who may benefit from supplementation.(10)

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Bio-D-Mulsion 1000®

Proven Safe and Effective in the Treatment of Hypovitaminosis D Among Otherwise Healthy Infants and Toddlers

Safe - Conservative regimen of **Bio-D-Mulsion 1000®** supplies necessary vitamin D (as emulsified D3) without the increased risk of hypercalcemia commonly associated with single, large dose therapies — especially important in an outpatient setting.*

Additionally, **Bio-D-Mulsion 1000®** contains no artificial colorants or flavorings and no propylene glycol.

Effective - In the US, One (1) drop daily of **Bio-D-Mulsion Forte®** (2,000 IU) increased 25(OH)D concentrations in vitamin D deficient children 202% in six weeks, effectively tripling 25(OH)D levels.*

Easy to Administer for Greater Compliance - Simply dispense one (1) drop from the bottle directly onto the tongue each day.*

**Gordon CM, et al.Treatment of Hypovitaminosis D in Infants and Toddlers J Clin Endocrin Metab. First published ahead of print April 15, 2008 as doi:10.1210/jc.2007-2790*

Cost Effective - Of the three regimens tested, the one using **Bio-D-Mulsion 1000®** is by far the most cost effective. (less than a nickel per day — less than $1.50 per month!)

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Study Summary - Vitamin D Treatment in Young Children

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Treatment of Hypovitaminosis D in Infants and Toddlers

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Introduction

Vitamin D deficiency, or hypovitaminosis D, appears to be on the rise in young children, with an increased prevalence noted among African American breastfed infants residing in northern latitudes.[1] This deficiency has been identified as the leading cause of rickets among infants, as breast milk contains inadequate amounts of vitamin D to support skeletal health in this age range.[2,3] Furthermore, numerous sources of evidence now indicate that vitamin D (cholecalciferol) has several important physiologic effects beyond calcium absorption and bone maintenance,[4,5] and early vitamin D repletion through supervised supplementation may have a positive impact on later neurologic health,[6,7] immune function,[8,9] and chronic disease risk.[10,11] With the reemergence of hypovitaminosis D among infants and toddlers, questions regarding the most appropriate treatment regimen require clarification.

The aim of the present study was to examine prospectively three common treatment short-term regimens for correction of hypovitaminosis D in infants and toddlers. We conducted a randomized clinical trial, treating participants with either daily low dose of vitamin D_2, a higher dose of vitamin D_2 once weekly, or a low dose of vitamin D_3 once daily. This study examined: 1) the efficacy of each treatment in raising serum 25(OH)D and lowering parathyroid hormone (PTH) concentrations; and, 2) the safety and tolerance of each regimen in infants and toddlers, as evaluated through documentation of hypo- or hypercalcemia and reported symptoms.

Research Design and Methods

Subjects

During the cross-sectional screening portion of the study, 380 infants and toddlers, aged 8-24 months, were enrolled consecutively throughout the calendar year from the Children's Hospital Boston Primary Care Center between October 2005 and June 2007. Exclusion criteria for the study included having a chronic disease (e.g. asthma, seizure disorder, sickle cell disease), or the use of oral glucocorticoid over the previous 3 months, or other therapy known to affect vitamin D metabolism. Patients found to be vitamin D deficient (25(OH)D ≤ 20 ng/mL [50 nmol/L]) were invited to participate in the randomized clinical trial which included randomization to one of three vitamin D treatment regimens. The Committee on Clinical Investigation, Children's Hospital Boston, approved the study protocol, and parents or guardians of all participants provided written informed consent.

Treatment Protocol

Patients identified to have hypovitaminosis D were randomly assigned to one treatment protocol. The vitamin D treatments included one of three regimens: 2,000 IU oral ergocalciferol (vitamin D_2) daily, 50,000 IU vitamin D_2 weekly, or 2,000 IU cholecalciferol (vitamin D_3) daily. Each group was also prescribed 50 mg/kg/day of elemental calcium to prevent hypocalcemia associated with 'hungry bone' syndrome.[12] Infants received the combined vitamin D and calcium treatment for a course of 6 weeks.

Vitamin D and calcium supplements were each provided in a liquid suspension that was administered orally from a vial directly onto the tongue. The vitamin D_2 preparation (200 IU per drop or 0.025 mL) was manufactured by Sanofi-Synthelabo Inc. (Bridgewater, NJ), and doses were provided as 10 drops or 0.25 mL daily for the 2,000 IU dose and 6.25 mL weekly for the 50,000 IU dose; for each vitamin D_2 dose. The vitamin D_3 (2,000 IU per drop, oil and water emulsion) was provided by Biotics Research Corporation (Rosenberg, TX) and one drop or 0.025 mL was administered daily from the vial directly onto the child's tongue. Assays of products ensured potency. Two comparisons were formally designated as being of primary interest: daily vitamin D_2 vs weekly vitamin D_2, and daily vitamin D_2 vs daily vitamin D_3.

Laboratory Measurements

During the baseline and follow-up visits, one blood sample (15 mL) was obtained from each subject. Laboratory samples were processed immediately at both Children's Hospital Boston and ARUP Laboratories (Salt Lake City, UT). Serum 25(OH)D levels were measured at ARUP Laboratories, using a Diasorin chemiluminescent assay (LIAISON®; DiaSorin Inc, Stillwater, MN). This assay accurately quantifies the sum of both 25(OH) D_3 and 25(OH)D_2. A multi-channel analyzer (Roche Diagnostics, Indianapolis) was used to measure serum calcium, phosphorus, magnesium, and alkaline phosphatase levels on site. Intact PTH was measured by a 2-site chemiluminescence immunoassay (Nichols Institute, San Clemente, CA).

Results

Subjects

Within our clinical sample of 380 infants and toddlers,[13] we identified 40 infants and toddlers to have hypovitaminosis D (25(OH)D ≤ 20 ng/mL [50 nmol/L]). Within this sample of 40 participants, 35 completed the course of therapy (87.5%). All three treatments virtually tripled the 25(OH)D concentration in these vitamin D deficient children. The greatest effect was attained with weekly vitamin D_2: from 13.8 to 44.0 ng/mL, an increase of 220%. The next greatest was the effect of D_3 (13.7 to 41.2 ng/mL, 202%), followed by daily vitamin D2 (15.7 to 43.9 ng/mL, 182%). Daily vitamin D_2 showed an effect 12% lower than weekly vitamin D_2 (p=0.66) and 7% lower than daily D_3 (p=0.82).

Calcium

Baseline calcium concentrations were compared to the current trial participants, each with hypovitaminosis D, to 329 vitamin D replete subjects. The mean change in serum calcium levels was small and similar in the three treatment groups (-3% for vitamin D_2 daily, +3% vitamin D_2 weekly, +1% vitamin D_3 daily).

Parathyroid Hormone (PTH)

Eight participants (20%) presented with elevated PTH at baseline (reference range 10-65 pg/mL). All cases returned to normal limits following treatment. There was no significant difference in PTH suppression among the three groups (p=0.74).

Alkaline Phosphatase

There was no significant impact of treatment on alkaline phosphatase concentrations.

Discussion

To our knowledge, this study is the first to compare the efficacy and safety of three common short-term treatment regimens to correct hypovitaminosis D in infants and toddlers. We report no difference in outcome between vitamin D_2 daily, vitamin D_2 weekly, or vitamin D_3 daily for a sample of young children. Our study showed that each treatment regimen was equally effective, as well as safe. These data are reassuring to providers, as vitamin D_2 daily or weekly, or vitamin D_3 daily, combined with elemental calcium, appears to provide an effective and well-tolerated treatment for correcting hypovitaminosis D in infants and toddlers.

Our data provide clinical guidance regarding the appropriate dosage range of vitamin D to treat deficiency in this young population. Among infants, hypercalcemia has been reported with the administration of single high-dose therapy of 300,000 IU[14] or 600,000 IU,[15] as well as daily doses exceeding 10,000 IU daily.[16] While a single 600,000 IU dose has been strongly advocated by one group as a safe regimen and one that eliminates the problem of noncompliance,[18] this recommendation has been met with controversy and, specifically, concerns about hypercalcemia,[14, 17] especially in an outpatient setting. In our study, we report a surprising higher overall incidence of mild hypercalcemia at baseline in contrast to after treatment. All subjects were asymptomatic. There was no statistically significant correlation between the presence of hypercalcemia at baseline and following each tested course of treatment. Therefore, these more conservative regimens of vitamin D_2 daily, vitamin D_2 weekly, or vitamin D_3 daily may provide the necessary treatment without the increased risk of hypercalcemia commonly associated with single large dose therapies (also known as stosstherapy).[18] The potential toxicity associated with stosstherapy is further underscored by a recent report that showed hypercalcemia in an infant treated with the equivalent of 4 daily stosstherapy doses.[19]

In summary, we demonstrate that 2,000 IU daily vitamin D_2, 50,000 IU vitamin D_2 weekly, or 2,000 IU daily vitamin D_3 yield equivalent outcomes in the short-term treatment of hypovitaminosis D among otherwise healthy infants and toddlers. These results indicate that pediatric providers can determine the appropriate method of treatment for a given patient or family to ensure compliance. The argument favoring large dose depot therapies for correcting hypovitaminosis D must be reevaluated, as more conservative lower dose therapies may provide a safer method of treatment, especially in the outpatient setting, without the associated risk of hypercalcemia. We recommend early treatment with one of these three treatment regimens, or subtle variations to the dosages studied, to prevent the potential skeletal and extraskeletal problems associated with hypovitaminosis D. Lastly, we do not endorse the use of the current relatively high doses of vitamin D for the long-term prevention of hypovitaminosis D in infants and young children.

Acknowledgments: We wish to acknowledge

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Bio-D-Mulsion 1000® is available in 1 ounce bottles (#1012).

Supplement Facts

Serving Size: 1 Drop (0.04 mL)

	Amount Per Serving	% Daily Value
Vitamin D (as cholecalciferol)	50 mcg	250%

Other ingredients: Water, gum arabic and sesame seed oil.

Bio-D-Mulsion 1000® is an oil-in-water emulsion. Vitamin D oil has been dispersed into microscopic particles to aid absorption and assimilation.

This product is gluten and dairy free.

RECOMMENDATION: One (1) drop each day as a dietary supplement or as otherwise directed by a healthcare professional.

This product is intended to be used under the direction and supervision of a healthcare professional. Use only as recommended unless otherwise directed.

KEEP OUT OF REACH OF CHILDREN
Store in a cool, dry area.
Sealed with an imprinted safety seal for your protection.

Product # 1012 Rev.12/18

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