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Perspective Open Access

A Newly Developed Dimer of Vitamin D Combined with N-Acetylgalactosamin-Albumin Protein Carrier is a Safe and Conciliable Method to Rapidly Provide Cholecalciferol to the Human Body

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Perspective

Vitamin D helps to regulate the amount of phosphate and calcium in the body. Deficiency of vitamin D leads to rickets in children and osteomalacia in adults. Bone pain and muscle weakness are the symptoms of vitamin D deficiency. Calcium along with Vitamin D helps to build bones and keep bones strong and healthy. Vitamin D may also play a prominent role in immune system and the proper muscle function. The immune system is the body's defense system. Low vitamin D deficiency is extremely common worldwide [1,2]. Additionally, low vitamin D status is strongly associated with increased risk of for non-musculoskeletal and musculoskeletal chronic diseases [3-6]. To follow oral absorption, metabolism and tissue distribution in patients or human volunteers, radiolabelled cholecalciferol testing was used [7-9]. If given with milk or long-chain fatty acid containing triglycerides the absorption of orally applied vitamin D3 between 3 µg daily and 1 mg (40000 I.U.) weekly is estimated to be between 60 and 99% but is strongly dependent on the bile acid and cholesterol secretion capacity of the liver and pancreatic sufficiency [10,11]. Because current indoor lifestyle, sun avoidance/sunscreen use and clothing choices, severely limit sun exposure-dependent vitamin D production, vitamin D supplementation is often essential.

It has long been assumed that vitamin D intestinal absorption is a passive process, but new data shows that it is actually far more complex than previously thought [12]. Although recent data significantly improves our understanding of vitamin D intestinal absorption, further studies are required to increase our knowledge of the molecular mechanisms [12].

Therefore, we tried to develop a possibility to administer Vitamin D orally and possibly in an iv-version with a water-soluble preparation by building a cholecalciferol with a recombinantly produced protein, deriving from GC-protein. Previous pre-clinical toxicology studies of human N-acetylgalactosamin-albumin (Gc globulin) in mice, rats, guinea pigs, rabbits and Shetland ponies showed no toxic effects [13]. Therefore, Phil et al., concluded that the safety profile of N-acetylgalactosamin-albumin (Gc globulin) appears to be consistent to that required for use in human [13]. To achieve a sufficient Vitamin D supplementation without the known side effects, we developed the Vitamin D N-acetylgalactosamin-albumin dimer, which has been proven to be safe, reconcilable and effective, among others, e.g., in normal persons and in autistic children under oral supplementation [14].

To prove the safeness of Cholecalciferol supplementation with Vitamin D oral and iv.-supplementation as a newly developed dimer including an N-acetylgalactosamin-albumin dimer protein carrier, we performed a controlled study in normal human persons and a placebo- controlled mice study. In 52 normal human persons the formulation was very well conciliable and no negative side effect occurred. Furthermore, after five weeks of bi-weekly injection also no side effects could be observed using Vitamin D N-acetylgalactosamin-albumin dimer injections, especially not any signs of hypervitaminosis or electrolyte disturbance or interference. At the end of the study, all blood results were within the normal range. Animals in the treatment groups showed a significant elevation of Vitamin D. In the Vitamin D N-acetylgalactosamin-albumin dimer group the Vitamin D level was double the value of the control group than control.

Therefore, we conclude that this newly developed complexed Cholecalciferol is a safe, conciliable and highly effective method in oral or iv.-substitution of Vitamin D. Further investigations have to be performed to verify the value in treatment of Vitamin D deficiency related diseases.

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