Treatment of non-alcoholic steatohepatitis patients with vitamin D: a double-blinded, randomized, placebo-controlled pilot study

Andreas Geier, Mareile Eichinger, Guido Stirnimann, David Semela, Fabian Tay, Burkhardt Seifert, Oliver Tschopp, Heike Bantel, Daniel Jahn, Ewerton Marques Maggio, Lanja Saleh, Heike A Bischoff-Ferrari, Beat Müllhaupt & Jean-François Dufour

BACKGROUND
Non-alcoholic steatohepatitis (NASH) is defined by liver inflammation and consecutive fibrotic damage caused by a deposition of fat in the liver. No licensed medical treatments exist and lifestyle modification is difficult to incorporate into everyday life. We investigated the efficacy and safety of a 48-week treatment with vitamin D3 in NASH patients.

METHODS
Histologically determined NASH patients with elevated alanine aminotransferase (ALT) and decreased 25-OH vitamin D level at baseline received vitamin D3 or placebo orally over a 48-week period. The primary endpoint of this study was the change in ALT from baseline to the end-of-treatment. Steatohepatitis was categorized according to the Steatosis, Activity and Fibrosis Score and disease activity was assessed using the NAFLD activity score.

RESULTS
Serum 25-OH vitamin D levels significantly increased only in the vitamin D3 group over the 48-week treatment phase indicating compliance. In contrast to placebo, patients in the vitamin D group had markedly decreased ALT levels after the end-of-treatment phase. A significant decrease during treatment with vitamin D was also observed for cytokeratin-18 fragments compared with placebo. The study was not powered to detect changes in histological score, hence only descriptive results for histopathological characteristics are available.

CONCLUSIONS
Treatment with 2100 IE vitamin D q.d. over 48 weeks was well tolerated and led to a significant improvement of serum ALT levels in patients with hypovitaminosis D and histology-proven NASH as the primary endpoint together with a trend toward reduction of hepatic steatosis, which was not significant due to a small number of available biopsy specimens.
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