

High dose UDCA therapy does not improve overall liver histology in obesity related hepatitis

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Results of a German study presented today at the International Liver Congress 2010, the Annual Meeting of the European Association for the Study of Liver in Vienna, Austria, have shown that overall, treatment with high dose (23-28mg/kg/d) ursodeoxycholic acid (UDCA) is no more effective than placebo in the treatment of non-alcoholic steatohepatitis (NASH), the most advanced form of non-alcoholic liver disease associated with cirrhosis of the liver .

NASH is a serious development of non-alcoholic [fatty liver disease](#) (NAFLD), the most common persistent liver disorder in western countries and for which there is no proven medical therapy. Results from this study show that high dose UDCA - a naturally occurring bile acid, historically used to treat gallstones - is not superior to placebo therapy. Moderate histological and biochemical improvement was only observed in a subgroup of mildly overweight male patients.

Commenting on the study, Professor Fabio Marra of the EASL scientific committee said: "The use of UDCA is still considered controversial in non-alcoholic hepatitis, although previous research has suggested that the treatment may have some beneficial effects. The results of this study indicate that high dose UDCA is not superior to placebo except in a small subset of individuals. Nevertheless, the results do provide some interesting clinical pointers for clinicians in this field."

In the study, patients with histologically proven NASH (n=186, 147 of whom proceeded to treatment) were organised according to gender, body weight, liver biochemistry and histology and were randomised to receive either 23-28mg/kg/d UDCA or placebo for a period of 18 months.

Pre- and post-treatment [liver biopsies](#) from 139 patients were analysed, the primary evaluation criteria was an improvement in liver histology and secondary criteria were improvements in NASH-associated histological findings and liver function test results.

No significant difference was seen in overall liver histology or biochemistries between the two treatment groups. Interestingly, beneficial results were seen in intra-acinar inflammation (inflammation of the functional units of the liver) and levels of the enzyme gamma glutamyltransferase (a marker for liver cell damage) in a small population of younger, mildly overweight males, indicating that UDCA therapy may be potentially useful for these patients.

The incidence and prevalence of NASH is increasing , in parallel with rising levels of obesity - one of the main risk factors for NASH . With this in mind, it is important to identify effective treatment options to improve the management of patients and prevent progression to cirrhosis - an irreversible condition with liver transplant the only definitive treatment.

More information:

References:

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