primary studies - published RCT

Ursodeoxycholic acid for liver disease associated with cystic fibrosis: a double-blind multicenter trial. The Italian Group for the Study of Ursodeoxycholic Acid in Cystic Fibrosis.

Code: PM8675168 **Year:** 1996 **Date:** 1996 **Author:** Colombo C

Study design (if review, criteria of inclusion for studies)

double-blind, multicenter randomized controlled trial

Participants

12 centers, 55 CF patients with liver disease (39 male subjects; median age, 13.8 years).

Interventions

Patients were randomly assigned to receive for 1 year one of the following treatments: UDCA (15 mg/kg body weight daily) plus taurine (30 mg/kg body weight daily), UDCA plus placebo, placebo plus taurine, or double placebo.

Outcome measures

Clinical and laboratory evaluations were performed every 3 months.

Main results

After 1 year, deterioration of overall clinical conditions, as indicated by the Shwachman-Kulczycki score (SKS), occurred in patients who received placebo but not in those who received UDCA (P = .025). Patients treated with UDCA also showed an improvement in gamma-glutamyl transpeptidase (GGT) (P = .004) and 5'-nucleotidase (P = .006) levels. Treatment with taurine was followed by a significant increase in serum prealbumin levels (P = .053), a trend toward a reduction in fat malabsorption, and no effect on the biochemical profile. No severe side effects occurred with any treatment.

Authors' conclusions

UDCA administration improves clinical and biochemical parameters in CF patients with liver disease. Taurine supplementation may be indicated in patients with severe pancreatic insufficiency and poor nutritional status.

http://dx.doi.org/10.1002/hep.510230627

See also

Hepatology. 1996 Jun;23(6):1484-90.

Keywords

Adolescent; Adult; Child; Cholagogues and Choleretics; Combined Modality Therapy; Gastrointestinal Agents; Gastrointestinal Diseases; Liver Diseases; non pharmacological intervention - diet; pharmacological_intervention; Supplementation; taurine; UDCA; Malabsorption; Nutrition Disorders; Amino Acids; Proteins;