primary studies - published RCT

A controlled trial of ursodeoxycholic acid treatment in cystic fibrosis-related liver disease.

Code: CN-00196428 **Year:** 1992 **Date:** 1992 **Author:** O'Brien S

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

RCT

Participants

Inclusion criteria: participants with CF (diagnosed by sweat test and clinically) and with liver disease. This was defined as large liver, greater than 12 cm on physical examination and/or large spleen, palpable on examination and confirmed by abdominal ultrasound and/or raised liver enzymes for at least 6 months (gamma glutamyl transferase above 50 IU/l, 5'nucleotidase over 15 IU/l). 12 participants recruited. Age range 12 - 42 years (median 19.5 years). 11 out of 12 participants had advanced liver disease - portal hypertension and/or histological features of fibrosis or cirrhosis.

Interventions

UDCA: 20 mg/kg/day for 6 months. Control: No additional therapy.

Outcome measures

Weight gain, triceps skinfold thickness, mid-upper arm circumference, subscapular skinfold thickness, liver enzymes, biliary excretion.

Main results

UDCA treatment was associated with significant improvements in 5'nucleotidase, gamma-glutamyl transferase, aspartate aminotransferase and alanine aminotransferase levels which were not observed in the control group. After 6 months the hepatic clearence of technetium 99 (Tc99) diisopropylphenyl-carboxymethyl iminidodiacetic acid (DISIDA) at 45 and 60min as an index of biliary excretion and the plasma disappearance rate of indocyanine green as an index of hepatic function were unchanged in both groups. Body weight increased to a similar degree in both treatment and control groups, mean percentage change in body weight 7.6 plus or minus -3.3% and 11.9 plus or minus -3.4%, respectively (P = NS), an effect attributable, at least in part, to the intensive dietary advice and supervision given to all patients throughout the study period.

Authors' conclusions

Although improvements in liver biochemistry may be anticipated with UDCA therapy, further controlled studies are required to determine if long-term administration of UDCA influences hepatocellular function, biliary excretion or nutrition.

http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/428/CN-00196428/frame.html

See also

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Keywords

Adolescent; Adult; Child; Cholagogues and Choleretics; Gastrointestinal Diseases; Liver Diseases; non pharmacological intervention - diet; pharmacological_intervention; UDCA; Gastrointestinal Agents;