primary studies - published RCT

Bioavailability of oral vitamin E formulations in adult volunteers and children with chronic cholestasis or cystic fibrosis.

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

2-way open randomized single dose cross-over trial (1 week washout period).

Participants

12 healthy volunteers and 6 children with chronic cholestasis and 6 children with cystic fibrosis. CF ascertained either by sweat test or genotyping; pancreatic insufficiency determined by at least one functional pancreatic test. Age: birth to 15 years. CF participants mean (SD) age: 89.8 (56.5) months.

Interventions

Drugs: tocofersolan vs water miscible formulation of vitamin E. Dose: 100 IU/kg of vitamin E using an oral administration, maximum dose of 2000 IU.

Outcome measures

Vitamin E plasma concentration measured at 3, 6, 9, 12 and 24 hours after oral administration.

Main results

In healthy volunteers, formulations were not bioequivalent with a higher exposure to tocofersolan. In cholestatic children tocofersolan bioavailability was significantly higher than reference formulation (maximum plasma concentration: P = 0.008 and AUC: P = 0.0026). Bioavailability was not statistically different in cystic fibrosis.

Authors' conclusions

Oral tocofersolan was more bioavailable than the reference formulation in children with chronic cholestasis and similarly bioavailable in cystic fibrosis. Tocofersolan may represent an alternative to painful intramuscular vitamin E injections in chronic cholestasis, or to other oral formulations in cystic fibrosis.

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See also

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Keywords

Adolescent; Adult; Child; Cholestasis; Gastrointestinal Diseases; Infant; Liver Diseases; non pharmacological intervention - diet; Oral; vitamins; Vitamin E; Vitamins; Antioxidants;