

Cochrane Database of Systematic Reviews - - Cochrane Review

Inhaled antibiotics for the treatment of chronic *Pseudomonas aeruginosa* infection in cystic fibrosis patients: challenges to treatment adherence and strategies to improve outcomes.

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

Randomised controlled trials, quasi-randomised controlled trials (including cross-over trials (to be judged on an individual basis))

List of included studies

Koletzko 1990

Participants

Children and adults with CF diagnosed by sweat test or genetic testing, with all stages and severity of lung disease and with or without pancreatic sufficiency.

Interventions

Different treatment groups of enteral laxative therapy for preventing DIOS (including osmotic agents, stimulants, mucolytics and substances which have more than one action) at any dose to placebo, no treatment or an alternative oral laxative therapy.

Outcome measures

Primary outcomes: complete or incomplete DIOS diagnosed either clinically (e.g. abdominal masses, or distension or pain) or radiologically (e.g. dilated bowel or faecal mass). Adverse effects from treatments: serious adverse effects of treatment regimens (including, but not limited to, rectal bleeding, intestinal perforation, mucosal erosions, anaphylactic reaction, vomiting with electrolyte disturbance); other adverse effects of treatment (e.g. diarrhoea or soiling, abdominal distension, loss of continence or pain). Secondary outcomes: time to hospital admission. Patient-reported quality of life (QoL) scores. Patient-reported symptom scores. Tolerability (participant- or investigator-reported rates of concordance).

Main results

We included one cross-over trial (17 participants) with a duration of 12 months, in which participants were randomly allocated to either cisapride (a gastroprokinetic agent) or placebo for six months each. The trial had an unclear risk of bias for most domains but had a high risk of reporting bias. Radiograph scores revealed no difference in occurrence of DIOS between cisapride and placebo (narrative report, no data provided). There were no adverse effects. Symptom scores were the only secondary outcome within the review that were reported. Total gastrointestinal symptom scores favoured cisapride with a statistically significant mean difference (MD) of 7.60 (95% confidence interval (CI) 4.73 to 10.47). There was no significant difference at six months between cisapride and placebo for abdominal distension, MD 0.90 (95% CI 2.39 to 0.59) or abdominal pain, MD 0.4 (95% CI 2.05 to 1.25). The global symptom scores (whether individuals felt better or worse) were reported in the paper to favour cisapride and be statistically significant (P

Authors' conclusions

There is an absence of evidence for interventions for the prevention of DIOS. As there was only one included trial, we could not perform a meta-analysis of the data. Furthermore, the included trial compared a prokinetic agent (cisapride) that is no longer licensed for use in a number of countries due to the risk of serious cardiac events, a finding that came to light after the trial was conducted. Therefore, the limited findings from the trial are not applicable in current clinical practice. Overall, a great deal more research needs to be undertaken on gastrointestinal complications in CF, as this is a very poorly studied area compared to respiratory complications in CF

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See also

Patient Prefer Adherence. 2016 Feb 16;10:183-93. doi: 10.2147/PPA.S53653. eCollection 2016.

Keywords

Osmotic laxatives; Lactulose; Macrogol 3350; Diatrizoate; Stimulant laxatives; Senna; Sodium docusate; Sodium picosulphate; Mucolytics; Oral N-acetylcysteine; Laxatives; Gastrointestinal Agents; pharmacological_intervention;