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Cystic Fibrosis Research News

Title:
Rates of adverse and serious adverse events in children with cystic fibrosis

Lay Title:
Adverse events in clinical trials in children with CF

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What was your research question?
We wanted to understand how often adverse events were reported in clinical trials involving children with CF.

Why is this important?
Children with CF are being included in clinical trials frequently, and adverse events occur frequently in CF. In order to understand if adverse events are related to new therapies being studied, it is important to understand how often adverse events are reported in children with CF not taking investigational therapies.

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What did you do?

We reviewed adverse events reported in two studies of children with CF. We grouped adverse events according to the ages of the children in the studies, the organ systems involved, the severity of lung disease, and the season of the year.

What did you find?

We found that adverse events are reported very often in studies of children with CF. Respiratory symptoms were most commonly reported, with most children with CF reporting new or worsening cough in the first four months of the studies. Adverse events occurred less in the summer compared to spring, fall, and winter.

What does this mean and reasons for caution?

These background rates of adverse events may be used to understand the potential adverse effects in future drug studies in children with CF. Short clinical trials could be affected by the season in which children with CF are enrolled. These results are based on studies that occurred more than 10 years ago, and adverse events may be affected by current therapies, especially highly effective modulators.

What's next?

These results may need to be re-evaluated in studies of children with CF who are taking highly effective modulators.

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