Cystic Fibrosis Research News

Title:
CLOFAZIMINE FOR TREATMENT NTM INFECTIONS IN CHILDREN WITH AND WITHOUT CYSTIC FIBROSIS

Lay Title:
Clofazimine use for treatment of mycobacteria in children with and without cystic fibrosis

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What was your research question(s)?
Can children with and without Cystic Fibrosis (CF) be treated with usual doses of clofazimine at a normal interval? Is it safe to use clofazimine in children and adolescents with and without CF? Do children with and without CF tolerate and have any bad side effects while taking clofazimine?

Why is this important?
Clofazimine is an oral antibiotic used to treat leprosy. It is now being used to treat other bacteria in the leprosy family (called *Mycobacteria*). Clofazimine is not available in regular pharmacies and needs special approval for doctors to be able to prescribe it. Clofazimine is being used more often to treat children with mycobacterial infections. Currently, clofazimine is given with other oral and inhaled medicines to children after completing 2-3 months of multiple intravenous medications. No one knows how safe clofazimine is in children, the best dose to use, or when to give clofazimine to children with or without CF.

What did you do?
We gave clofazimine to 10 children (8 with CF, 2 without CF). At first, all of the children received usual doses of clofazimine (based on their weight). We asked the children to take

the clofazimine with a high-fat meal. At their clinic appointments we checked for any dangerous reactions to the medicine. We also measured clofazimine levels in the blood 2-4 weeks after they started the medicine, 2-3 hours and 6-7 hours after they took clofazimine. Based on those blood levels, all children with CF needed higher doses of clofazimine. We then checked their clofazimine blood levels again.

What did you find?

Clofazimine is safe to give to children with and without CF. None stopped clofazimine due to a bad reaction. Children without CF, who were treated with usual doses of clofazimine, had normal clofazimine levels in the blood 2-4 weeks after starting the medicine. Children with CF who were treated with usual doses of clofazimine had low clofazimine levels at 2-4 weeks, or even after 3 months of treatment. After increasing the clofazimine dose in 4 children with CF, 2 had normal clofazimine levels and 2 had near normal clofazimine levels <4 weeks after receiving a higher dose.

What does this mean and reasons for caution?

Clofazimine is safe to use in children. No children had serious side effects or requested to stop the clofazimine treatment. In our study, we found that children without CF could receive usual doses of clofazimine and had normal clofazimine levels, as expected. Children with CF needed higher doses of clofazimine than is currently recommended. In addition, the children with CF had to take the clofazimine longer to achieve normal (or near normal) levels in the blood. This means children with CF may need clofazimine treatment sooner than is currently recommended (prior to stopping intravenous antibiotic therapy).

What's next?

More studies should be done to: 1) learn why there is a difference in clofazimine levels in children with CF; 2) find the best clofazimine dose for children with CF 3); and, recommend the best timing to start clofazimine in children with CF for the treatment of mycobacterial infections.

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