



Cystic Fibrosis Research News

Title:

Testicular pain following initiation of elexacaftor / tezacaftor / ivacaftor in males with cystic fibrosis

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What was your research question?

Our article describes previously unreported possible side effects of mental status changes with elexacaftor/tezacaftor/ivacaftor (Trikafta). We included details on when these possible side effects occurred, as well as what next steps were taken when patients reported it.

Why is this important?

Members of the Cystic Fibrosis care team, patients, and their families should be aware that mental status changes such as mental fogging, word-finding difficulty, and memory issues were reported by patients while taking elexacaftor/tezacaftor/ivacaftor (Trikafta). It remains inconclusive if these symptoms were related to the medication, so it is important that other patients who experience similar possible side effects and their CF care teams report them to the manufacturer so additional data can be collected.

What did you do?

We reviewed what is currently known about how other medications cause mental status changes. We hypothesized how elexacaftor/tezacaftor/ivacaftor (Trikafta) might cause them. We summarized our patients' experiences with these possible side effects, including when it started and what was done to manage it.

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What did you find?

Patients reported a slow or delayed onset of mental status changes, but noted that this possible adverse effect did begin within the first 3 months after starting elxacaftor/tezacaftor/ivacaftor (Trikafta). At this time, there is no specific recommended management of this possible side effect. Most patients wanted to stay on the medication due to improvements in their lung function or other CF-related symptoms. To accommodate patient's wishes, CF care teams sometimes suggested alternatives to the FDA-approved labeling of the medication (ex. reduced doses or alternate timing) to see if that would help alleviate the possible side effects.

What does this mean and reasons for caution?

The underlying mechanism responsible for this possible side effect remains unknown. While patients may wish to remain on the medication, alternatives to the FDA-approved labeling of the medication have not been tested to determine if they are still helpful for improving lung function.

What's next?

Further research is needed to evaluate the specific impact of this medication on the central nervous system, and whether or not these possible side effects have other long-term implications.

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