



Cystic Fibrosis Research News

Title:

MATERNAL AND FETAL OUTCOMES FOLLOWING ELEXACAFTOR-TEZACAFTOR-IVACAFTOR USE DURING PREGNANCY AND LACTATION

Lay Title:

IMPACT OF TRIKAFTA ON MOTHERS AND BABIES DURING PREGNANCY AND LACTATION

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What was your research question?

We aimed to determine if it is safe for women with CF and their babies for these women to continue Trikafta during pregnancy and breastfeeding.

Why is this important?

Animal studies showed that Trikafta crosses the placenta and is present in breastmilk. Babies of animals exposed to Trikafta at normal human doses during pregnancy did not have birth defects. However, Trikafta has not been studied in pregnant people or women who are breastfeeding, so the risks to the developing and/or breastfeeding baby are unknown. On the other hand, previous data shows that some people with CF who suddenly stop taking their modulators become ill. For this reason, it is difficult for women with CF to know if they should continue or stop their modulators during pregnancy and breastfeeding.

What did you do?

We sent a 2-page questionnaire to CF clinical care providers regarding women with CF who continued Trikafta during pregnancy and/or lactation. Without providing any names or dates of birth, center staff answered questions regarding women's ages, CF mutations, duration of use of Trikafta during pregnancy, whether the mother or baby experienced any complications during pregnancy or breastfeeding and whether any complications that occurred were thought to be related to use of Trikafta.

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What did you find?

We received 45 responses on pregnancies during which the baby was exposed to Trikafta for some or all of the pregnancy. There were two accidental pregnancies that occurred after women started Trikafta which resulted in termination. Complications in 2 of the mothers and in 3 of the infants were thought to possibly or likely be related to Trikafta. Five of the six women who stopped taking Trikafta because of the unknown risks to their babies decided to restart during pregnancy because they became ill. Twenty-six babies were exposed to Trikafta during breastfeeding. No complications were reported following exposure.

What does this mean and reasons for caution?

Many women with CF are expressing desire to have children, and pregnancy rates are increasing. Complications of pregnancy for women and their babies are common for women with CF, especially in the setting of maternal diabetes or low lung function. Following Trikafta exposure during pregnancy or breastfeeding, caregivers considered very few complications to be possibly or likely related to Trikafta use. However, this study was very small. Larger studies are needed to determine if the benefits (mom's health stability) of Trikafta use during pregnancy and breastfeeding outweigh any potential risk to the health of her baby.

What's next?

Maternal and Infant Outcomes in the Era of Modulators (MAYFLOWERS) is a CFF-funded large, prospective (following women and their babies forward in time), multicentre study. As part of the study, we will collect data to evaluate the impact of Trikafta use during pregnancy and lactation on women and their babies.

Original manuscript citation in PubMed

<https://pubmed.ncbi.nlm.nih.gov/33762125/>