primary studies - published, non RCT

Pregnancy among cystic fibrosis women in the era of CFTR modulators.

Code: PM28190780 **Year:** 2017 **Date:** 2017 **Author:** Heltshe SL

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

Study from Cystic Fibrosis Foundation Patient Registry

Participants

CF women

Interventions

ivacaftor

Outcome measures

Pregnancy

Main results

Among women with CF, ages 15-44years, there was a slight downward trend in annual pregnancy rates from 2005 to 2014 (2% reduction per year, p=0.041). Among women with G551D, pregnancy rates during phase 3 ivacaftor trial years was 14.4/1000 women-years compared to 34.0/1000 prior to the trial period (relative risk [RR]=0.65; 95% CI=0.43-0.96; p=0.011) and 38.4/1000 after drug approval in June 2012 (RR=1.52 post-approval compared to trial period; 95% CI=1.26, 1.83; p

Authors' conclusions

Evidence of significantly increased numbers of pregnancies among women taking approved CFTR modulators is important because of the unknown risk to pregnancy and fetal outcomes. Increases may be temporary following pregnancy prevention during controlled clinical trials, or from altered perceptions about maternal survival with new approved treatments. As more women with CF become eligible to receive modulators, the CF community must study their effect on contraceptive efficacy and safety during pregnancy. With increased health and survival due to modulation, family planning topics will become more common in CF.

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See also

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Keywords

Child; Adult; Adolescent; Aminophenols; CFTR Modulators; Genetic Predisposition to Disease; Orkambi; pharmacological_intervention; VX-770; ivacaftor; lumacaftor; VX-809; Pregnancy;