

**EMBARGOED FOR RELEASE UNTIL FRIDAY, JULY 30, 2021, AT 10:30 A.M. EDT**

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**LATE-BREAKING CLINICAL TRIAL RESULTS ANNOUNCED  
AT HEART RHYTHM 2021:**

**NEW CLINICAL TRIAL SHOWS INCREASED RISK OF CARDIAC EVENTS AMONG  
WOMEN WITH LONG QT SYNDROME TAKING ORAL CONTRACEPTIVES**

*Study offers a comparison of oral contraceptives by formulation type*

**BOSTON, MA, July 30, 2021** – Results from a new clinical trial show an increased risk of cardiac events, like sudden cardiac death (SCD), among women with congenital long QT syndrome (LQTS) who are taking progestin-only oral contraceptives (OC) without beta-blocker therapy. The trial is the first to assess the association of OCs by formulation type on the risk of cardiac events in female patients with congenital LQTS. Findings from this clinical trial were presented today as late-breaking science during Heart Rhythm 2021 and simultaneously published in *Heart Rhythm Journal*.

LQTS is an inherited heart rhythm condition that can potentially cause abnormal heartbeats. It can cause seizures, fainting and even can cause cardiac events like syncope, aborted cardiac arrest (ACA) and SCD.<sup>1</sup> Women with congenital LQTS are at an increased risk of cardiac events after the onset of adolescence, possibly due to effects of estrogen and progesterone on cardiac potassium channels. Use of OC could modulate those effects, but there is no data on the clinical effect of OC use by formulation type in LQTS.

The female-specific study evaluated women between 15 and 40 years old who were enrolled in the Rochester LQTS Registry beginning in 2010 with follow up reported through March 2021. Information on OC use, the onset of adolescence, pregnancy and menopause was obtained and type of OC was categorized as progestin-only, estrogen-only or combined. Andersen-Gill multivariate modeling was used to evaluate the association of time-dependent OC use with the burden of cardiac event.

Of the 1,659 women with LQTS (39% LQT1, 35% LQT2, 11% LQT3), 370 (22%) were treated with an OC at any time during follow-up. During a cumulative follow-up of 35,797 years, there were a total of 1,977 cardiac events. The multivariate analysis showed the progestin-only OC was associated with 2.6-fold increased risk of cardiac event among women who did not receive beta-blocker therapy (HR=2.63 [95% CI 1.19-5.78]; p=0.01). Beta-blocker therapy was highly protective among women taking a progestin-only OC (HR=0.22; [95% CI 0.07-0.74]; p=0.01). Estrogen-only OC and combined OC were not associated with increased cardiac event rates compared to women not taking OCs, regardless of beta-blocker treatment. An important additional finding from this study is that the risk associated with OC use was most pronounced in LQT2 women, who share a similar risk mechanism as patients who experience drug-induced long QT syndrome.

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<sup>1</sup> Mizusawa Y, Horie M, Wilde AA. Genetic and clinical advances in congenital long QT syndrome. *Circulation journal: official journal of the Japanese Circulation Society*. 2014;78(12):2827–33. pmid:25274057.

“Seeing the increased cardiac event risk among women using progestin-only oral contraceptive was a surprise for our research team. These findings have the potential to change how physicians prescribe oral contraceptive medications to their female patients with LQTS,” said lead author Ilan Goldenberg, MD, University of Rochester Medical Center. “Because sudden cardiac death often occurs in patients without structural heart disease and in the absence of other causes, we hope that studying LQTS as a mechanism of sudden cardiac death will help physicians better understand and treat this patient population.”

The authors of this study believe these results underscore the need for physicians across specialties to work together to evaluate the risk among different types of oral contraceptives to better treat patients. The authors also believe the results of their trial have further implications beyond OCs and congenital LQTS and would like to see further investigation into drug-induced LQTS and how other medications, like antibiotics and anti-anxiety treatments, could also impact this condition.

**Sessions Details:**

“Late-Breaking Clinical Trials 3: Updates: *Oral Contraceptive Use And The Risk Of Cardiac Events In Women With Congenital Long Qt Syndrome*” [Friday, July 30, 2021 at 10:30 a.m. EST]

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About Heart Rhythm 2021

The Heart Rhythm Society's annual meeting attracts thousands of the world's finest clinicians, scientists, researchers, and innovators in the field of cardiac pacing and electrophysiology. Heart Rhythm 2021 attendees were able to determine how to participate - virtually or in-person. More than 600 international experts in the field will serve as faculty for programing that includes Daily Plenary Sessions, Late-Breaking Clinical Trials, Recorded Cases, Debates, Rhythm Theater Presentations and more, while over 100 exhibitors will showcase innovative products and services.

About the Heart Rhythm Society

The Heart Rhythm Society is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients and is the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. Incorporated in 1979 and based in Washington, D.C., it has a membership of more than 7,000 heart rhythm professionals in more than 90 countries around the world. For more information, visit [www.HRSonline.org](http://www.HRSonline.org).