

Exhibit 589

Prevalence of and risk factors for self-reported menstrual changes following COVID-19 vaccination:
a Danish cohort study

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Prevalence of and risk factors for self-reported menstrual changes following COVID-19 vaccination: a Danish cohort study

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Abstract

STUDY QUESTION

Are there some characteristics that render individuals more susceptible to report menstrual changes following the Coronavirus disease 2019 (COVID-19) vaccination?

SUMMARY ANSWER

We found that 30% of menstruating women reported menstrual changes following COVID-19 vaccination and several potential risk factors including stress, vaccine concerns, severe COVID-19 infection, and immediate vaccine symptoms were associated with these reports.

WHAT IS KNOWN ALREADY

Studies suggest that COVID-19 vaccination might temporarily prolong menstrual cycle length by less than 1 day. Specific characteristics may trigger menstrual changes in temporal relation to the vaccination simply by chance or render women more vigilant to potential menstrual changes after being vaccinated. However, research investigating potential risk factors for reporting menstrual changes following COVID-19 vaccination is limited.

STUDY DESIGN, SIZE, DURATION

A population-based Danish cohort study. Data were collected from May 2021 to December 2021 as a part of the BiCoVac Cohort with the aim of examining non-specific effects following COVID-19 vaccination. The main study population included 13 648 menstruating women aged 16–65 years who completed all surveys, received their first dose of a COVID-19 vaccine during the data collection period, and completed questions related to their menstrual cycle.

PARTICIPANTS/MATERIALS, SETTING, METHODS

Potential risk factors included 14 biological, physical, or psychological measures. Information on most potential risk factors was self-reported and collected before the participants' first COVID-19 vaccination. Information about any menstrual change following COVID-19 vaccination was self-reported at the end of the data collection period. Logistic regression analyses were used to estimate crude and adjusted odds ratios (ORs) with 95% CIs for the association between each potential risk factor and reporting menstrual changes following COVID-19 vaccination.

MAIN RESULTS AND THE ROLE OF CHANCE

Any menstrual change following COVID-19 vaccination was reported by 30% of menstruating women. Most of the potential risk factors were associated with reports of menstrual changes following COVID-19 vaccination. In particular, higher odds were found among women who reported ≥ 5 immediate vaccine symptoms; OR 1.67 [1.50–1.86], had had a prior severe COVID-19 infection; OR 2.17 [1.40–3.35], had a high-stress level at baseline; OR 1.67 [1.32–2.10], or were concerned about COVID-19 vaccines prior to vaccination; OR 1.92 [1.50–2.45]. Lower odds were found among women with regular menstrual cycles using hormonal contraception; OR 0.71 [0.65–0.78].

LIMITATIONS, REASONS FOR CAUTION

We were unable to address the causal effect of COVID-19 vaccination on the reported menstrual changes, as information

about menstrual changes was not available among non-vaccinated women.

WIDER IMPLICATIONS OF THE FINDINGS

The study identified several potential risk factors for reporting menstrual changes following COVID-19 vaccination. Further studies are needed to establish causal associations and the clinical impact of self-reported menstrual changes.

STUDY FUNDING/COMPETING INTEREST(S)

The BiCoVac data collection was funded by TrygFonden (id-number: 153678). No competing interests are declared.

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