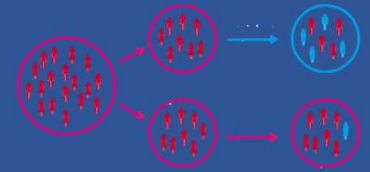




The University of
Nottingham

Recruitment of pregnant women to randomised trials of COVID-19 treatments, and pharmaceutical treatments received outside such trials: A Research Article

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Study objectives:

1. To document how many pregnant women with COVID-19 participated in randomised trials.
2. To document what treatments were received outside the trials.
3. Compare the treatments received with evidence-based treatment recommendations.



Methodology:

- Two clinical trial registries were searched to identify COVID-19 trials open to pregnant women.
- Studies were extracted from scientific case reports and case series of maternal COVID-19 in pregnancy to identify trial enrolment and the pharmaceutical treatments received outside trials.

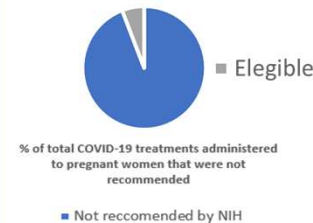
ISRCTN registry

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Results:

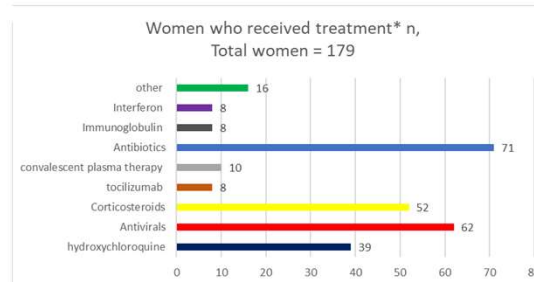
Proportion of pregnant women with COVID-19 who were eligible to a RCT



Of 179 case reports of women with COVID 19 in pregnancy, 109/179 women received ≥ 1 COVID-19 pharmaceutical treatment.

156 studies (case reports, case series and registries) reporting 43,185 pregnant women with COVID-19. Of these, 2,671 (6.2%) were potentially eligible for a randomised trial but only seven (0.26%) enrolled.

A COVID-19 pharmaceutical treatment was administered 1,296 times outside of a trial. In 566 (44%) cases the treatments were not recommended by the National Institutes of Health (NIH) at the time of administration.



Significance:

Our findings support previous reports of gross underrepresentation of pregnant women in clinical trials, including COVID-19 trials.

The exclusion from trials did not protect women from harmful treatments. For example, chloroquine is now 'associated with an increased length of hospital stay' (1).

Conclusions:

Whilst we recognise legitimate concerns regarding potential harm to the fetus, consideration must also be given to the inevitable damage caused by excluding a population from research.

The exclusion may lead to the use of ineffective or harmful medications outside of trials.

References:

1. RECOVERY Collaborative Group. Effect of Hydroxychloroquine in Hospitalized Patients with COVID-19: Preliminary results from a multi-centre, randomized, controlled trial. MedRxiv. 2020.