



Press Release

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Regarding the Creinin et al Mifepristone antagonization study (1), we wish to challenge some of the authors' conclusions regarding the safety and efficacy of progesterone used to reverse the effects of mifepristone in women who change their minds after starting a medical abortion. This study does make it clear that taking mifepristone and doing nothing else does pose a risk to the pregnant woman.

It should be noted that among the twelve subjects, the one who required the blood transfusion and suction aspiration (surgical abortion) was in the placebo group and did not receive progesterone. Two other subjects were transported by ambulance to the emergency department. One, in the progesterone group, represented a failed abortion reversal. For "brisk bleeding" she called the ambulance. In the emergency department, she was noted to have completed her abortion and did not require suction aspiration. The third patient was in the placebo group, was transported by ambulance, and required suction aspiration.

Two voluntarily exited the study. One patient, in the placebo group, "had increased anxiety about bleeding . . . and requested a suction aspiration." The other patient who voluntarily exited the study was in the progesterone group and had increased nausea and vomiting, requiring intravenous fluids as an outpatient. She also requested a suction aspiration.

Therefore, the only patients who required (not requested) suction aspiration before completing the study were in the placebo group. The progesterone patient with nausea and vomiting requested the suction aspiration and the one with the failed reversal did not have a suction aspiration.

As for effectiveness, after excluding the two who voluntarily withdrew from the study (one in the placebo group and one in the progesterone group), four of the five (80%) who received progesterone had surviving embryos. This is consistent with Delgado et al's 2018 study with a 68% live birth rate after treatment with the same oral progesterone protocol used in the Creinin study. (2) The embryo survival of two of five (40%) in the placebo group is consistent with the historic survival rate of 25% for embryos exposed to mifepristone only in the early studies conducted before misoprostol was added to the medical abortion regimen.(3) An "intention-to-treat" analysis that includes the two who voluntarily exited shows four of six (67%) embryos in the progesterone group survived, while only two of six (33%) in the placebo group survived.

This study, although not reaching statistical significance, certainly supports the earlier research demonstrating the effectiveness of using progesterone in women who wish to reverse their mifepristone abortions. This study also demonstrates the hazards of having a placebo group which, from a maternal safety standpoint, fared poorly compared to the progesterone group.

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1. Creinin MD, Hou MY, Dalton L, Steward R, Chen MJ. Mifepristone antagonization with progesterone to prevent medical abortion: a randomized controlled trial. *Obstet Gynecol* 2020;135
2. Delgado G, Condly S, Davenport M, Tinnakornsriruphap T, Mack J, Khau V, Zhou P. A case series detailing the successful reversal of the effects of mifepristone using progesterone. *Issues in law and Medicine*, 2018, 33 (1)
3. Davenport M, Delgado G, Khau V. Embryo survival after mifepristone: review of the literature. *Issues in Law and Medicine* 2017, 32 (1): 3-18.