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Dear Colleague,

Thank you for seeing this patient. She has taken mifepristone, the first part of the two-step Mifegymiso medical abortion drug protocol.

She has decided that she would like to reverse the effects of mifepristone to attempt to stop the medical abortion process.

Provided that she has not taken the second medication, misoprostol, and provided that it has been less than 72 hours since she took the first medication, you can help her do just that, easily and safely.

She needs supplemental progesterone to counter the effects of mifepristone, which is a progesterone receptor antagonist. Neither progesterone nor mifepristone has been associated with any birth defects.¹

Progesterone Protocols Based on Published Data

Based on these new data, two reasonable preferred protocols can be suggested for women who seek to reverse the effects of mifepristone. (An information sheet on the protocol is attached.)

- 1. Progesterone micronized 200 mg capsule two by mouth as soon as possible and continued at a dose of 200 mg capsule two by mouth twice a day for three days, followed by 200 mg capsule two by mouth at bedtime until the end of the first trimester.
- 2. Progesterone 200 mg intramuscular as soon as possible and continued at a dose of 200 mg intramuscular once a day on days two and three, then every other day for a total of seven injections.²

If the patient does nothing and does not take the second medication, embryo survival is about 25%.³ If she is given the above regimen of progesterone, the rate of survival increases to approximately between 55-70%.⁴ Your help is invaluable, but time is of the essence, so please do not delay.

If you require more information, there exists an information line on the medical abortion reversal procedure at 1-877-558-0333. Phones are answered seven days a week.

Sincerely,

The Board of Directors Canadian Physicians for Life

¹ Progesterone. https://www.asrm.org/detail.aspx?id=1881(accessed December 3, 2016). Progesterone package insert. https://www.drugs.com/pro/progesterone-capsule.html. (accessed December, 3, 2016).

² A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone, <u>Issues in Law & Medicine</u>, <u>Volume 33</u>, <u>Number 1</u>, 2018.

³ Embryo Survival after Mifepristone: A systematic review of the literature, Issues in Law & Medicine, Volume 32, Number 1, 2017.

⁴ A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone, <u>Issues in Law & Medicine</u>, <u>Volume 33</u>, <u>Number 1</u>, 2018.



APPENDIX 8

PROGESTERONE PROTOCOLS FOR THE ATTEMPTED REVERSAL OFMIFEPRISTONE

Oral Protocol

- 1. Prometrium brand or progesterone generic micronized oral capsules 200 mg, two capsules (400 mg) by mouth ASAP and bedtime on day 1 (must be at least 5 hours apart). 200mg, two capsules (400 mg) AM and PM on day 2 and 3 .Do not prescribe if the patient is allergic to peanuts as it is made with peanut oil.
- 2. Continue progesterone200mg, two capsules (400mg) at bedtime until the end of first trimester or according to your clinical judgment.

Vaginal Protocol (Capsules per vagina)

- 1. If the patient is unable to take oral capsules or intramuscular injections, consider vaginal administration of oral capsules Prometrium brand or progesterone generic micronized oral capsules 200 mg, two capsules (400 mg) inserted vaginally ASAP AND at bedtime day 1 (must be at least 5 hours apart). 200mg, two capsules (400 mg) AM and PM on day 2 and 3. Do not prescribe if the patient is allergic to peanuts as it is made with peanut oil.
- 2. Continue progesterone 200mg, two capsules (400 mg) inserted vaginally daily at bedtime until the end of first trimester or according to your clinical judgment.

Intramuscular Protocol

- 1. Compounded progesterone in oil 200mg (100mg/ml or 50mg/ml) intramuscularly (IM) ventral or dorsal gluteal muscle, slowly over 2-3 minutes as soon as possible after the ingestion of mifepristone.
- Continue progesterone in oil, 200 mg IM once a day for two more days.
- 3. Continue progesterone in oil, 200mg IM every other day until day 14 after mifepristone ingestion.
- 4. Continue progesterone in oil, 200 mg IM twice a week until the end of the first trimester. Consider tapering the progesterone after the first trimester, according to your clinical judgment.

Additional Instructions:

- If prescribing oral, prescribe enough for 1 week at a time with refills. One month's supply may be unaffordable if the patient's insurance doesn't cover.
- Provide ultrasound per clinic protocol as soon as possible to confirm embryonic viability and intrauterine location. If <u>less</u>
 than 6 weeks after LMP, consider monitoring serial HCG levels and simply do ultrasound at 6 weeks.
- If bleeding or cramping occurs and an intrauterine location of pregnancy has not been confirmed, treat as an ectopic pregnancy and appropriately refer until an intrauterine location is confirmed.
- For an ectopic pregnancy or an incomplete abortion, seek consultation as necessary.
- Provide an ultrasound every 1-2 weeks during the first trimester to confirm continued viability.
- The physician, midwife, PA or NP who prescribes must see the patient within 72 hours of the initiation of the protocol.
- Approved: George Delgado, MD, FAAFP Medical Director APR

01-29-18 N

Next review: 01-29-20