



ORIGINAL ARTICLE

Progesterone after mifepristone: A pilot prospective single arm clinical trial for women who have changed their mind after commencing medical abortion

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Abstract

Aim: This pilot study aimed to assess the utility of an oral progesterone treatment protocol for women who commenced medical abortion and then changed their mind and wished instead to maintain their pregnancy.

Methods: The Progesterone-After-Mifepristone—pilot for efficacy and reproducibility (PAMper) trial was designed as a prospective single-arm pilot clinical trial, conducted via telehealth. Women aged 18 to 45 years in Australia who reported ingesting mifepristone within the last 72 h to initiate medical abortion and had not taken misoprostol were included. Initial contact was by a web-based form. Following informed consent, participants were prescribed oral progesterone to be taken 400 mg twice per day for 3 days then 400 mg at night until completion of a 19 day course. Pregnancy viability was assessed by ultrasound scan after 14 days of progesterone treatment.

Results: Between October 2020 and June 2021, nine women contacted the PAMper trial, of whom six enrolled and commenced progesterone treatment. These women reported ingesting mifepristone at 40–70 days of gestation, with progesterone being commenced within 5.7–72 h of mifepristone ingestion. Five participants had ongoing, live pregnancies at the primary endpoint (ultrasound at >2 weeks). One participant had a miscarriage after 9 days of progesterone treatment. There were no clinically significant adverse events.

Conclusion: This small study demonstrated a clinically sound protocol for researching the use of progesterone-after-mifepristone for women in this circumstance. Results of this pilot study support the need for further larger scale trials in this field.

KEYWORDS

abortion seekers; abortion, induced; abortion, threatened; family planning; mifepristone; pregnancy outcome; reproductive health autonomy; threatened miscarriage; unplanned pregnancy; unwanted pregnancies

INTRODUCTION

Early medical abortions are increasing in Australia (1) with prescriptions increasing from 26 000 in 2019 to 31 000 in 2021 (2). In the two stage medical abortion regimen women take 200 mg of mifepristone, followed 36 to 48 h later by 800 µg of misoprostol (3). In the time

between taking mifepristone and being due to take misoprostol, a small number of women decide to discontinue their abortion and seek options to maintain the viability of their pregnancy, which has become an iatrogenic threatened miscarriage (4,5). The exact number of women who commence medical abortion and then decide to discontinue is unknown. It is suggested that figures

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from the US drug distributor cited in the literature (6,7) underestimate actual numbers (5).

Mifepristone has an anti-progestational action by antagonizing the endometrial and myometrial effects of progesterone. Since mifepristone is a high-affinity competitive antagonist at progesterone receptors, high concentrations of progesterone could be expected to compete with mifepristone and potentially counter its embryocidal effects at progesterone receptors (8).

In exercising their reproductive autonomy, women who decide to access a medical abortion may seek support for a subsequent decision to discontinue a medical abortion. Women discontinuing a medical abortion can then (1) do nothing further, (2) access surgical abortion, or (3) access therapy to try and maintain a viable pregnancy (9). Treatment with progesterone in this circumstance has at times been referred to as “abortion reversal.” The largest report published on progesterone therapy after mifepristone-alone ingestion detailed results for 547 women of whom 257 (48%) had resultant live births (4). This low-level data suggests that the use of progesterone may potentially present a low-risk therapeutic option for women who decide to discontinue an early medical abortion.

The present pilot study aimed to assess the safety and effectiveness of a clinical trial protocol for the therapeutic use of progesterone in women who commenced medical abortion, then subsequently changed their minds, and wanted to continue their pregnancies.

METHODS

Progesterone-After-Mifepristone—pilot for efficacy and reproducibility (PAMper) was a single-arm clinical trial approved by the University of New England Human Research Ethics Committee (HE20-101) for the period 25th August 2020 to 25th August 2021. It was conducted by telehealth in Australia, accessed via the internet and only advertised via social media.

Participants entering the PAMper trial had defined contacts with the Trial Coordinator, Primary Care Provider (PCP), and their nominated medical practitioner (Figure 1). Women wanting to continue their pregnancy after taking mifepristone contacted the Trial Coordinator by completing a web form on the PAMper website (pamtrial.org.au). The web form detailed the inclusion criteria: women aged 18 to 45 years; ingested mifepristone within the last 72 h and had not taken misoprostol; no contraindications to progesterone use (i.e., allergy to progesterone, sunflower oil, soya lecithin, gelatin, glycerol, or titanium dioxide); and ability to provide the name of a nominated medical practitioner for continuity of care. Women were then contacted by the Trial Coordinator by phone, discussing all three available options for their early pregnancy, and those eligible and interested were provided with trial information. They were informed that progesterone use was off-label, that there was no guarantee their treatment would result in an ongoing pregnancy, and that

there was currently only limited published evidence of benefit for pregnancy survival.

Following collection of electronic consent, participants were referred for a telehealth appointment with a PAMper PCP. This consultation was conducted to assess the woman's clinical state, including her mental and emotional wellbeing, and to confirm trial eligibility. Women satisfying eligibility criteria and wishing to proceed with progesterone therapy were provided with instructions for trial participation and a prescription for progesterone. If medical or psychological health issues were identified during consultations, referrals were made to appropriate clinical or support services.

The PAMper trial was prospectively registered on the Australian New Zealand Clinical Trials Registry (ACTRN12620000596909).

Treatment regimen

A high dose oral progesterone regimen was chosen for this study based on use in a recent randomized controlled trial (6) and a reported pregnancy continuation rate of 68% (4). Proprietary 100 mg soft capsules are convenient to administer and available through community pharmacies in Australia.

The regimen was 400 mg (four capsules) twice per day for 3 days, then 400 mg at night until 19 completed days of therapy.

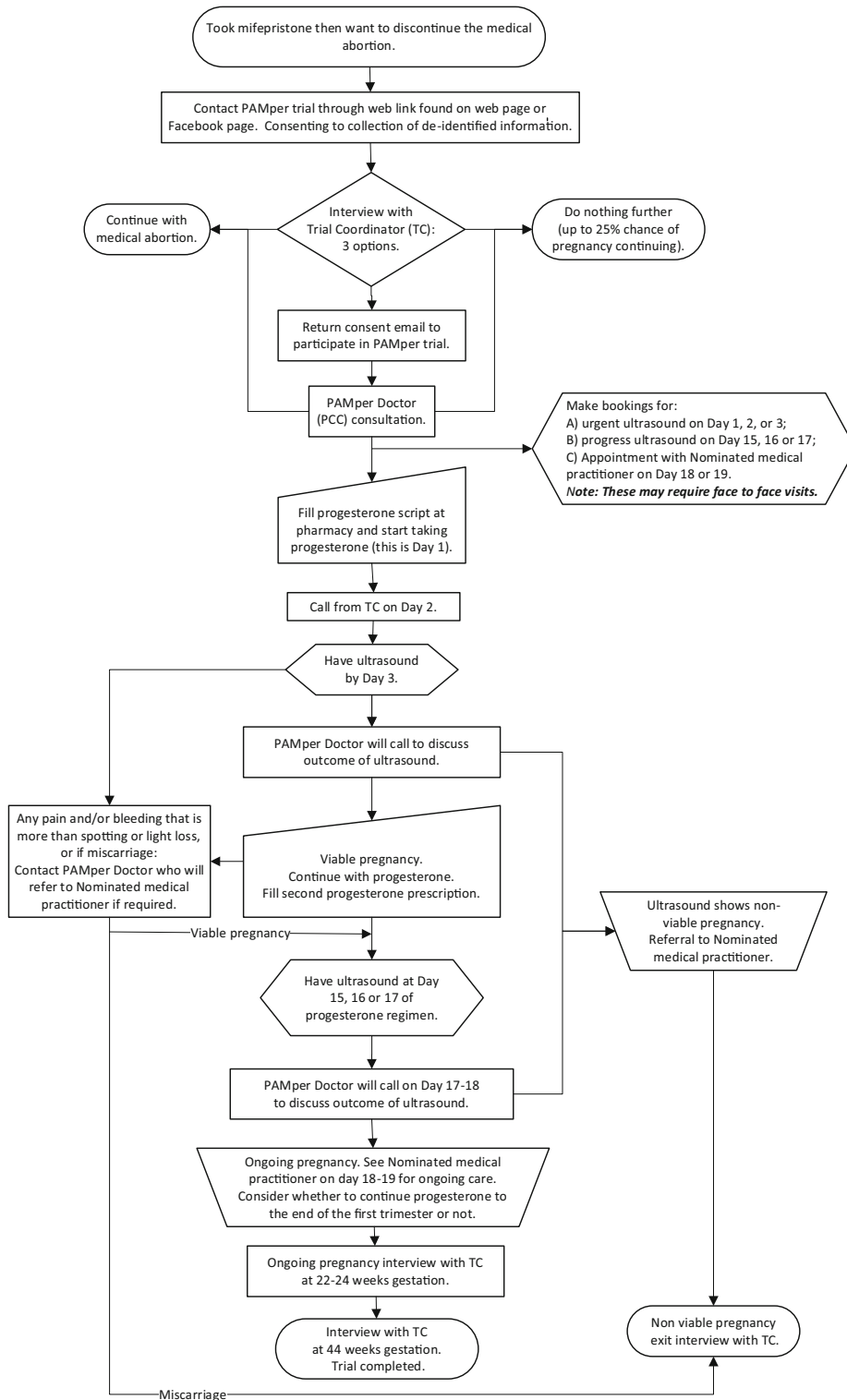
During the trial, women were referred by the PCP to their nominated medical practitioner for ongoing care. Referral was made either routinely, or expeditiously in the case of a participant needing prompt medical or psychological care. It was expected that participants were to see their nominated medical practitioner for the provision of antenatal and emergency care throughout and beyond the course of the trial, as required.

Clear clinical pathways were in place for women presenting with bleeding or cramping. Women without an intrauterine location of pregnancy confirmed (prior to or during care) were to be treated as for a pregnancy of unknown location with an appropriate referral (hospital Early Pregnancy Assessment Service or Emergency Department). Those with known intrauterine pregnancy confirmed were to be managed as for threatened miscarriage, with consideration for ultrasound and human chorionic gonadotropin (hCG) monitoring to determine viability. Specialist consultation was sought as necessary.

Sample size

Sample size was determined using sample size tables for phase II clinical trials (10). Continuation of pregnancy has been reported to be 0%–25% if mifepristone is used alone up to 49 days gestation (6,11). We considered a clinically significant pregnancy continuation rate would be 50%, which is a more conservative figure than has

FIGURE 1 Contacts and participants in the PAMper trial.



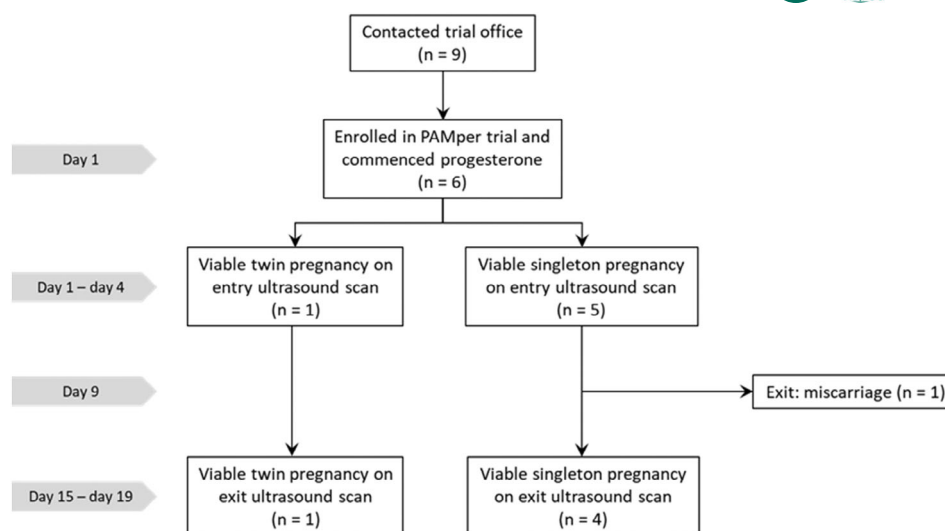
been reported previously (4), and would be unlikely to raise unrealistic expectations in the women; thus safeguarding their mental wellbeing.

Assuming 25% of pregnancies would continue without intervention, a clinically significant response for viability after oral progesterone of 50%, 80% power and $\alpha = 0.05$, a sample size of 26 would be required with a cut off of 11 (10).

Data management and analysis

Data collected included: pelvic ultrasound scan within 3 days of enrolment and at 15–19 days after initiation of progesterone; demographic and clinical data; decisional certainty scoring; and PCP and Trial Coordinator field notes. Data were de-identified for analysis and scoring of pregnancy viability at the primary endpoint

FIGURE 2 Participant flow diagram through the PAMper trial.



(>14 days after commencement of treatment) was allocated a random code that was not revealed to the investigators undertaking statistical analysis until analysis was complete. Data were collated and analyzed on Microsoft Excel v2023.

The percentage of participants with a viable pregnancy >14 days after commencing progesterone was compared with the minimum required percentage for effect of 25% using a chi-squared test, with an alpha of 0.05 representing a significant difference.

Adverse events were reported to the Data and Safety Monitoring Board (DSMB). At their discretion, the DSMB were able to advise on trial continuation or closure in the event of slow recruitment, adverse outcomes or null effect.

RESULTS

Between October 2020 and June 2021, nine women contacted the PAMper trial, of whom six proceeded to enroll and commence taking progesterone (Figure 2).

Participants had a median age of 26 years and largely came from metropolitan areas (Table 1). Mifepristone was taken between 40 and 70 days gestation (Table 2). Of the six women who entered the trial, five had ongoing pregnancies at >14 days after commencing progesterone treatment. There were no reports of clinically significant adverse events (Table 3).

Participant A expressed uncertainty about either aborting or continuing her (first) pregnancy. She delayed taking mifepristone until 70 days gestation, aware that it was licensed for use until 63 days gestation.

The PCP engaged with Participant B’s GP regarding antenatal and mental health issues. Participant B missed several night doses of progesterone throughout the trial period.

TABLE 1 Participant characteristics (n = 6).

Characteristic	Value
Age, years (median, range)	25.8 (22–33)
BMI, kg/m ² (median, range)	22.2 (20.8–29.0)
Location	
Metropolitan	5
Rural	1
Country of birth	
Australia	4 (1 Aboriginal and/or Torres Strait Islander)
UK	1
USA	1
Education level	
Secondary school	1
Technical and further education	4
University	1
Gravidity (prior to current pregnancy)	
Nulligravida	2
Primigravida	2
Multigravida	1
Previous abortion	1
Previous miscarriage	2
Gestation at mifepristone ingestion	
Days (median, range)	48 (40–70)
Time for progesterone after mifepristone	
Hours (median, range)	30.3 (5.7–72)
Mifepristone prescriber	
General Practitioner	3
Abortion clinic—in person	2
Abortion clinic—telehealth	1

Abbreviation: BMI, body mass index.

TABLE 2 Initial participant clinical data.

Participant	Gestation mifepristone was taken (d) ^a	Time to first progesterone dose (h) ^b	Entry ultrasound scan ^c	Entry ultrasound scan findings
A	70	34.5	Day 1	Live, 67 days gestation Small subchorionic hematoma. Cervix 55 mm long with external os 6 mm open
B	40	46	Day 4	Live, 41 days gestation Fetal heart rate 107 bpm
C	63	5.8	Day 2	Live, 67 days gestation
D	41/42	72	Day 3	Live, dichorionic diamniotic twins. Concordant dating, 61 days gestation (twin #1)
E	64	26.5	Day 3	Live, 64 days gestation
F	52	19–24	Day 1	Live, 53 days gestation

^aEither sonographic age relayed by the woman based on her pre-abortion dating ultrasound scan, or calculated from her last menstrual period.

^bCalculated from the time of mifepristone ingestion.

^cD1 was the first day of progesterone dosing.

TABLE 3 Clinical course and outcome data.

Participant	Phone consultations with PCP	Clinical issues	Exit ultrasound scan	Exit ultrasound scan findings
A	5	Vaginal spotting the night before commencing progesterone, which resolved by day 5.	Day 15	Live ongoing pregnancy, 76 days gestation.
B	6	Vaginal spotting and pelvic cramping after taking mifepristone and before commencing progesterone. Vaginal spotting resolved by day 6. Mild pelvic cramping throughout trial period.	Day 19	Live ongoing pregnancy, 58 days gestation.
C	8	Nausea since prior to mifepristone, with vomit on day 7. Mild pelvic cramping after taking mifepristone, resolved by day 3.	Day 15	Live ongoing pregnancy, 81 days gestation.
D	3	Increasing nausea.	Day 18	Live ongoing pregnancy, dichorionic diamniotic twins. Concordant dating, 82 days gestation (twin #1)
E	7	Nausea and vomiting since prior to mifepristone, and throughout the trial period. Vaginal spotting and pelvic cramping on days 3 and 4. Intermittent palpitations from day 8—considered likely recurrence of Grave's disease. No treatment.	Day 15	Live ongoing pregnancy, 72 days gestation.
F	6	Brief episode of mild pelvic cramping prior to commencing progesterone. Vaginal spotting from day 3. Increased vaginal bleeding on day 7. Vaginal bleeding and products of conception passed on day 9.	Day 9	Completed miscarriage at 62 days gestation

Abbreviation: PCP, primary care provider.

Participant C delayed taking mifepristone until 2 weeks after it was prescribed. She reported having felt immediate regret and that her partner then assisted her in seeking options and provided her with details for the PAMper trial.

Participant D had known intrauterine twin pregnancies and was seen at a hospital pregnancy assessment clinic on the second day after taking mifepristone. She was seeking active treatment to keep her pregnancy and she consented to participating in the PAMper trial after

seeing a second specialist Gynecologist upon a second presentation at the hospital clinic.

Participant E was prescribed mifepristone/misoprostol by telehealth and did not take mifepristone until 64 days gestation. She vomited immediately after her third dose of progesterone on day 2 of treatment but subsequently took another 400 mg of progesterone that morning. She self-presented to a hospital Emergency department for palpitations on day 8 which was thought to be due to her Grave's disease which had been unmedicated for the preceding 6 months.

Participant F had a miscarriage 5 years prior. She was on a depot antipsychotic for a longstanding mental health condition, and was given a dose on trial day 4. The PCP engaged with her regular psychiatrist and mental health case worker during the trial period. Participant F had transient vaginal blood loss with clots on day 7 and self-presented to a hospital emergency department. Ultrasound showed viable fetus with heart rate 122. She had further vaginal bleeding on day 9 and upon representation to the hospital her ultrasound scan showed an empty uterus. She did not require any intervention at either presentation and was given anti-D at an outpatient hospital clinic on day 10.

Five participants completed decision certainty scoring regarding their commencing progesterone treatment. All affirmatively answered that they:

- had enough support from others to make a choice,
- had enough advice to make a choice,
- were sure about what they chose,
- were clear about risks and benefits,
- were clear about what mattered most to them.

DISCUSSION

Pregnancy outcomes

Five of the six participants had ongoing pregnancies at the primary endpoint. While viability at 2 weeks is not a measure of live birth, it would be expected by that time for mifepristone to be eliminated sufficiently for it to have no further appreciable deleterious effect on the pregnancy. Therefore, identification of causation for miscarriage after this time should consider factors other than mifepristone.

Ongoing pregnancy viability rate did not reach statistical significance for determining treatment success. However, based on requirements for single-stage phase II designs (10), demonstrating a 70% continuation rate would require five pregnancy continuations from eight participants, while a 75% continuation rate would require four pregnancy continuations from six participants. Both these continuation figures were exceeded in this pilot study, with live pregnancy in five of six participants, providing supporting evidence for a larger trial in this field.

Mifepristone was ingested at 53 days gestation for the participant who had a miscarriage, and between 40 and 70 days gestation for the other participants who had ongoing pregnancies. It was not possible to draw conclusions about gestational age and likelihood of pregnancy termination due to the small numbers. Elsewhere, increasing pregnancy viability for increased gestation at the time of mifepristone ingestion has been noted (4).

Participant F had experienced a miscarriage at 7–8 weeks gestation previously. Her blood group was O negative and she had not previously received anti-D. She was also on depot parenteral antipsychotic treatment. Although there is little evidence for a class effect on pregnancy viability of second generation antipsychotics (12), an increased miscarriage rate for women taking aripiprazole has been reported (13).

Risks and adverse events

Progesterone use during pregnancy is considered safe on the basis of current evidence (14) and it is included in treatment guidelines for early pregnancy threatened miscarriage (15). However, given its longstanding and widespread use in fertility treatments and pregnancy, possible risks and harms continue to be explored (16). Neither progesterone (17) nor mifepristone have been associated with birth defects (18).

It was expected that a number of participants would experience bleeding and/or cramping, since these are commonly experienced after mifepristone ingestion or in miscarriage (19). There was no major hemorrhage or other clinically significant adverse events in the PAMper trial.

The only other published clinical trial for progesterone-after-mifepristone was stopped early for cited safety concerns (6). Of the 12 participants, three had clinically significant bleeding and presented to a hospital Emergency Room. Two in the placebo arm required suction aspiration, with one also requiring a blood transfusion. The other woman, who was taking progesterone, had her bleeding resolve spontaneously and she was discharged without intervention. These results highlighted the bleeding risk if mifepristone is not followed by a prostaglandin. However, this does not relate to safety in the PAMper trial which sought to provide a therapy, for which the bleeding risk has been reported to be less than that of placebo. Pre-abortion counseling for women prescribed mifepristone/misoprostol should have included potential adverse effects of the treatment, including hemorrhage, as well as the increased risk of severe bleeding if mifepristone was not followed by misoprostol. It is with this baseline risk that women who withdraw their consent for misoprostol then seek to take progesterone to maintain viability of their pregnancy.

Clinical follow up in the PAMper trial considered the participants' physical and mental health. Those with

mental health conditions required medication and/or psychological therapy. For these women, the PCP directly communicated with the participants' GP, psychiatrist, and case worker on an individual basis. When indicated, participants were also assisted in making timely appointments with their GP and/or mental health clinician.

Methodological considerations

The elimination half-life of mifepristone is 20 to 30 h (20) so it would be expected to be eliminated in 19 days. The longest reported half-life of mifepristone including metabolites is 90 h (3.75 days) (21) so 19 days supplementation would allow for five half-lives which was considered adequate for this study.

Current guidelines recommend telehealth as an option for provision of abortion services (22), and it is accepted internationally as safe approach (23). In Australia prescribers are required to ensure that women have 24 h access to the provision of surgical uterine evacuation or other interventions required for the management of complications of medical abortion (24). In rural and remote areas accessibility has been defined as being within 2 h of emergency care (25).

Questions regarding decisional certainty indicated that women seeking to participate in progesterone-after-mifepristone treatment were appropriately informed during the consent process, that they were adequately supported by others, and that they were certain about their decision to participate in the progesterone-after-mifepristone clinical trial.

Strengths and limitations

The sample population was small, representing 0.03% of the 29 770 prescriptions for mifepristone/misoprostol in Australia during the same time period (2). The study had a limited timeframe and recruitment strategy. Women have previously found "abortion reversal" services in Australia by internet searches rather than being referred (5). Women who have commenced medical abortion but who then wish to discontinue and maintain their pregnancy typically initially contact their abortion clinic or hospital emergency department. Clinicians in these locations may be unaware of the research in the use of progesterone in such circumstances and would be unlikely to know of the PAMper trial or how to refer women. The current pilot trial in maintaining impartiality, a strength, was not linked to abortion or "abortion reversal" services and thus was slow to recruit, a limitation. As a pilot trial, the study was limited to a small number of participants which did not enable statistical assessment of whether progesterone taken after mifepristone ingestion increased the rate of pregnancy viability.

A further issue was that ingestion of mifepristone was reported by the woman and was not able to be confirmed, as could be done in a randomized controlled trial (RCT). In this real-world study, participants were women seeking to keep their pregnancies, so a RCT design was neither feasible nor possible.

Ingestion of progesterone was also not able to be confirmed objectively. Elsewhere, increased serum levels of progesterone have been recorded within a few days of commencing oral progesterone after ingestion of mifepristone (6). Given that participants were invested in trying to maintain viability of their pregnancy by taking progesterone after mifepristone, their personal documented history of progesterone ingestion on the supplied administration-record was relied upon for the current study.

Research implications

Mifepristone/misoprostol is recently more readily available in Australia, with GPs, nurse practitioners and midwives now able to prescribe the combination regimen. Certification and registration requirements have also been removed for prescribers and dispensing pharmacists. An absolute increase in medical abortion rates is anticipated, with an expected commensurate small increase in the number of women who change their mind after taking mifepristone and who request treatment to try and maintain viability of their pregnancy. Thus, there is an increasing need for research into this area.

As a pilot trial, clinical recommendations cannot be made from the data presented. Further trials are required to determine pregnancy viability and live birth rates for women taking progesterone after mifepristone. Other questions include: the effect of time between mifepristone and progesterone ingestion; effect of gestational age on treatment/pregnancy outcomes; and utility of different progesterone dosage forms and treatment regimens.

For the small subset of women who commence medical abortion and then change their mind and wish to maintain their pregnancy, their clinical emergency is not addressed adequately by current practice guidelines. Our pilot telehealth study demonstrated a clinically and ethically sound protocol for researching the use of progesterone-after-mifepristone for women in this circumstance. Larger clinical trials are required to determine the clinical effectiveness of progesterone-after-mifepristone and, more importantly, how best to serve the health needs of women who decide not to continue with a medical abortion.

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CONFLICT OF INTEREST STATEMENT

M. Joy Spark, Deborah Garratt, and Anna Barwick declare that they have no competing interests. Joseph V Turner and Lucas A McLindon have previously served unpaid on the board of the Australasian Institute for Restorative Reproductive Medicine.

DATA AVAILABILITY STATEMENT

The data are not publicly available due to Human Research Ethics Committee (HREC) requirements regarding the sensitive nature of the research. Use of de-identified data may be granted for defined projects that meet governance and HREC requirements and approval. Requests/proposals for use of data should be submitted to contact@pamtrial.org.au.

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