

Comparing a 'wait and watch' approach vs medical treatment with misoprostol for first trimester retained products of pregnancy and using ultrasound to predict success

ACTRN12624001463561

Status	RECRUITING
Phase	Phase 4
Sponsor	Nepean hospital
Enrollment	80 participants

Plain Language Summary

After a miscarriage or termination of pregnancy in the first trimester, some tissue from the pregnancy can occasionally remain in the uterus — a condition called retained products of conception (RPOC). This can cause bleeding, pain, or a positive pregnancy test even after the pregnancy has ended. Traditionally, surgery (a procedure called D&C) has been the go-to treatment, but it carries a risk of uterine scarring (adhesions) that can affect future fertility.

This study is comparing two non-surgical approaches for managing RPOC: watching and waiting (expectant management) versus taking a medication called misoprostol that helps the uterus expel the remaining tissue. Participants will also have ultrasound scans used to help predict which approach is most likely to succeed for them. The study follows participants for 8 weeks to track whether the RPOC resolved without surgery, and monitors for any complications.

You may be eligible if you are aged 16 to 45 years and have been diagnosed with RPOC on ultrasound following a first-trimester miscarriage, medical management, or termination. You should have moderate or light bleeding, or persistent spotting or a positive pregnancy test beyond 3 weeks after the pregnancy. Women who choose surgical management, have allergy to misoprostol, or have signs of infection or haemodynamic instability would not be eligible.

Key Eligibility Criteria

Inclusion (15)

- Transvaginal ultrasound scan showing the presence of a measurable focus of hyperechoic material within the endometrial cavity WITH any of the following will be considered for recruitment:
- Symptomatic patients with moderate bleeding and/or pain presenting after 48 hours of antecedent events a-e:
- a. Spontaneous miscarriage
- b. Primary medical management of miscarriage - as per Mifemiso trial
- c. Primary surgical D&C for miscarriage
- ... and 10 more (see full listing online)

Exclusion (9)

- Women who choose surgical management for proven retained products of conception (RPOC) on transvaginal ultrasound (TVS)
- Allergies/ contraindications to the use of misoprostol
- Complete miscarriage on TVS or findings of uniform homogenous endometrium, with absence of vascularity and no measurable focus of hyperechoic material within the endometrial cavity or endocervical canal
- TVS showing only presence of avascular blood clot and absence of trophoblastic tissue irrespective of symptoms – given the difficulty in distinguishing between avascular blood clot and avascular trophoblastic tissue, recruiters will take a 2nd opinion from fellow recruiters prior to inclusion/exclusion
- Extrauterine pregnancy/ pregnancy of unknown location (PUL)

... and 4 more (see full listing online)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624001463561>

Locations (1 total)

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