

Reducing operative birth for fetal distress in women with small or suboptimally grown infants - The RidStress 2 Randomised Controlled Trial

ACTRN12621000354886

Status	RECRUITING
Phase	Phase 3
Sponsor	Mater Misericordiae Ltd
Enrollment	660 participants

Plain Language Summary

When a baby is smaller than expected (small for gestational age or growth-restricted), they are at higher risk of distress during labour — which can lead to emergency caesarean sections. This Phase 3 trial is testing whether sildenafil citrate (the active ingredient in Viagra) taken during labour can reduce the rate of emergency caesarean sections in women carrying small or growth-restricted babies. Sildenafil works by dilating blood vessels, which may improve blood flow through the placenta during the stress of labour contractions.

To be eligible, you must be 18 or older, pregnant with a single baby, planning a vaginal birth at term (37 weeks or more), and your baby must be suspected to be small for gestational age or have late fetal growth restriction based on ultrasound measurements.

Participants are randomly assigned to receive either sildenafil or a placebo during labour. The study is being run through Mater Misericordiae hospitals. Women taking nitrate medications, those who have had two or more previous caesareans, or those with a serious liver or kidney condition are not eligible. This research could help reduce the risks of emergency caesarean sections for both mother and baby when a small baby is identified in late pregnancy.

Key Eligibility Criteria

Inclusion (9)

- Singleton pregnancy
- Planning a vaginal birth at term (>37 weeks gestation)
- Aged >18 years and able to give informed consent
- Pregnancy complicated by suspected small for gestational age (SGA) infant or late fetal growth restriction (FGR) (see below definitions)
- SGA is defined as Estimated Fetal Weight (EFW) or Abdominal Circumference (AC) <10th centile for gestation based on ultrasound assessment.

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

Exclusion (6)

- Two or more previous CS births
- Previous classical CS
- Major fetal anomaly in this pregnancy
- Non-cephalic presentation
- Severe hepatic or renal impairment

... and 1 more (see full listing online)

Locations (4 total)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12621000354886>

Mater Mother's Hospital - South Brisbane, QLD, Australia

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Royal Brisbane & Womens Hospital - Herston, QLD, Australia
Sunshine Coast University Hospital - Birtinya, QLD, Australia
... and 1 more locations