

Continuous fetal heart rate Monitoring using non-invasive Fetal electrocardiography 3 (COMFY 3)

ACTRN12625001049460

Status	RECRUITING
Sponsor	Kali Healthcare
Enrollment	100 participants

Plain Language Summary

Monitoring a baby's heart rate during late pregnancy and labour is one of the most important ways to detect signs of distress early. The standard tool for this is cardiotocography (CTG), but it can be uncomfortable and requires gel pads on the belly. The Kali Monitoring System is a new device that uses non-invasive electrodes placed on the skin to detect the baby's heartbeat via fetal ECG — potentially offering a more comfortable and accurate alternative.

This study compares the Kali system directly against standard CTG in pregnant women who already need heart rate monitoring as part of their routine care. Researchers are assessing reliability, safety, and how easy the device is to use.

You may be eligible if you are at least 18 years old, are 32 weeks pregnant or more, are carrying a single baby, can read and understand English, and your doctor has already ordered CTG monitoring as part of your care. Women with a pacemaker or implanted electrical device, or who have skin irritation where the electrodes would be placed, are not eligible. This research could make fetal monitoring more comfortable for future mothers.

Key Eligibility Criteria

Inclusion (6)

- Pregnant women >/or equal to 18 years old
- Gestational age >/or equal to 32 weeks and 0 days
- Singleton pregnancy
- Ability to read and understand English
- Willingness to participate in the study
- ... and 1 more (see full listing online)

Exclusion (6)

- Implanted pacemaker or any other implanted electrical device
- Plurality higher than 1
- History of allergies to skin adhesives
- Irritated or lesioned skin at the electrodes locations
- Contraindication to the use of CTG
- ... and 1 more (see full listing online)

Locations (1 total)

Mercy Hospital for Women - Heidelberg, VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12625001049460>

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