

Evaluating the usability of a new U-shaped measuring tool for episiotomy: a mixed methods study

ACTRN12617000994381

Status	RECRUITING
Phase	Phase 1
Sponsor	Professor Ajay Rane
Enrollment	120 participants

Plain Language Summary

This study is testing a new measuring tool called the 'Episiometer' that helps midwives and doctors perform episiotomies (surgical cuts made during childbirth to help the baby out) at the correct angle. An episiotomy done at the wrong angle can lead to serious tears. Researchers want to find out whether this clear plastic tool, which is placed on the skin to guide the incision, is easy to use, helpful, and acceptable to both patients and clinicians.

You may be eligible if (as a patient):

- You are 18 years old or older
- You are pregnant and planning a vaginal delivery at Townsville Hospital
- You are at 28 weeks of pregnancy or beyond
- You can give informed consent

You may be eligible if (as a clinician):

- You are a doctor or midwife at Townsville Hospital who is qualified to perform an episiotomy

You may NOT be eligible if (as a patient):

- You are under 18 years old
- You have a mental impairment with no guardian or carer
- You do not speak English and cannot give consent

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (10)

- PATIENTS - PREGNANT WOMEN FOR PLANNED VAGINAL DELIVERY:
- The women need to be able to give valid informed consent to participate.
- Participants must be 18 years or older to be able to give consent.
- Women whose primary language is not English are likely to be coincidentally recruited, but women who do not have sufficient English language skills to understand the study's aims, risks and benefits, will not be able to give valid consent.
- Women who clinicians believe to be unable to consent (i.e mentally incapable) can still participate, as we have produced a patient carer information and consent form which can be filled in on their behalf.

... and 5 more (see full listing online)

Exclusion (6)

- PATIENTS:
 - I Children and/or young people (ie. <18 years)
 - People with an intellectual or mental impairment, where judgement of the participant's mental capacity is made by the clinician
- WHO DO NOT HAVE A GUARDIAN/CARER (as there is also a Patient Guardian/carer information sheet conveying the same <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12617000994381>)

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information as the Patient Information Sheet, but in a way that would allow a guardian/carer to consent for the participant - using the same normal consent form).

- Patients who do not speak English and are unable to give consent.

- CLINICIANS:

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

Locations (1 total)

The Townsville Hospital - Douglas, QLD, Australia