

Suck swallow breathe coordination in term breastfed infants with and without oral anomalies.

ACTRN12617000897369

Status RECRUITING
Sponsor A/Prof Donna Geddes
Enrollment 60 participants

Plain Language Summary

This study is looking at how tongue-tie (ankyloglossia) in newborn babies affects breastfeeding and whether a small procedure to release the tongue-tie (called a frenotomy) improves the baby's ability to suck, swallow, and breathe in a coordinated way during feeding. Breastfeeding can be painful and difficult when a baby has tongue-tie. This research will measure suction strength, tongue movement, milk intake, and nipple pain in mothers before and after the procedure.

You may be eligible if:

- You are an English-speaking mother with a baby under 12 weeks old
- Your baby was born at term (37 weeks or later) and weighs at least 2,500g
- You intend to breastfeed for at least 6 months
- Your baby is being breastfed (formula makes up less than half of feedings)
- A health professional has identified tongue-tie and breastfeeding difficulties in your baby

You may NOT be eligible if:

- You have had breast surgery or nipple piercing
- Your baby was born before 37 weeks of pregnancy
- Your baby was born weighing less than 2,500g
- Your baby has an acute illness, infection, or congenital condition
- You have multiple babies (twins, triplets)

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

Key Eligibility Criteria

Inclusion (1)

- English speaking mothers and their term infants less than 12 weeks of age; mothers who intend to breastfeed for at least 6 months, and infants are predominantly fed breastmilk (breastfeeding and/or expressed breastmilk, infant feeds comprise less than 50% infant formula). Ankyloglossia and breastfeeding difficulty will be identified by a health professional prior to enrolment.

Exclusion (2)

- Mothers with a history of breast surgery and/or nipple piercing
- Infants born <37/40 or <2500 g, acute illness, and/or infection and/or congenital disease or malformation, multiple birth infants.

Locations (1 total)

King Edward Memorial Hospital - Subiaco, WA, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12617000897369>

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