

Vitamin D supplementation to prevent acute respiratory infections among Indigenous children in the Northern Territory: a randomised controlled trial

ACTRN12618001174279

Status	RECRUITING
Phase	Phase 4
Sponsor	Menzies School of Health Research
Enrollment	314 participants

Plain Language Summary

This trial is investigating whether giving vitamin D supplements to Indigenous mothers during late pregnancy and to their babies in the first four months of life reduces the number of respiratory infections (coughs, colds, chest infections) that babies experience in their first year. Indigenous children in the Northern Territory have high rates of severe respiratory infections, which can lead to hospitalisation. Vitamin D plays an important role in immune function, and many Indigenous Australians have lower vitamin D levels, making this a potentially important and low-risk intervention.

Pregnant mothers between 28 and 34 weeks of pregnancy are randomly assigned to receive either weekly vitamin D supplements or a placebo (an identical-looking tablet with no active ingredient). After the baby is born, the baby also receives the allocated supplement or placebo until 4 months of age. Researchers track how many times the baby is seen for respiratory infections at hospitals or health centres in the first 12 months.

You may be eligible if you are an Aboriginal and/or Torres Strait Islander woman who is 28 to 34 weeks pregnant and living in or near Darwin, Alice Springs, or one of the participating communities. Women already taking high-dose vitamin D supplements, those with certain kidney conditions or hypercalcaemia, and those enrolled in other studies that might affect outcomes are not eligible.

Key Eligibility Criteria

Inclusion (8)

- Mother
- Pregnant with current gestation of 28 to 34 weeks, inclusive.
- Aged over 17 to less than or equal to 40 years at the time of written informed consent
- Aboriginal and/or Torres Strait Islander descent
- A resident in urban Darwin, Alice Springs or one of the participating communities at the time of enrolment and intending to stay in a study community until the infants is 12 months of age
- ... and 3 more (see full listing online)

Exclusion (20)

- Mother
- Enrolled in other studies that may influence the outcomes of this study
- Taking prescribed vitamin D in pregnancy >400 IU/day (or equivalent)
- Self-supplementing with vitamin D >400 IU/day (or equivalent) and not willing to cease
- Hypercalcaemia this pregnancy (serum calcium >2.8 mmol/L or a urinary calcium:creatinine ratio >1 on two occasions)
- ... and 15 more (see full listing online)

Locations (3 total)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12618001174279>

Royal Darwin Hospital - Tiwi, NT, Australia

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