

The Paracetamol and Ibuprofen in Kids Intervention (PIKI) Trial

ACTRN12624001055594

Status	RECRUITING
Sponsor	University of Auckland
Enrollment	1,086 participants

Plain Language Summary

When young children have a fever, parents and nurses want to make them comfortable — but which medicine works best for that? Paracetamol and ibuprofen are both commonly used, both proven safe, and both reduce fever. But no high-quality study has directly compared how well each one relieves discomfort and pain in babies and toddlers. The PIKI trial is designed to answer exactly that question.

Children attending emergency departments in New Zealand who are aged 2 to 23 months, have a temperature of 38°C or above, and appear noticeably uncomfortable will be randomly given either paracetamol or ibuprofen. Parents and nurses will not know which medicine was given. The main thing researchers are measuring is how much the child's discomfort improves over the following hours.

Your child may be eligible if they are aged 2–23 months, presenting to one of the participating New Zealand hospitals with a fever and signs of distress. Children who have already received the maximum dose of either medicine in the past 24 hours, or who have certain serious medical conditions, are not eligible.

Key Eligibility Criteria

Inclusion (4)

- Presenting to either Kidz First (Middlemore) ED, Starship Children's Hospital ED, Waitakere Hospital ED, Tauranga Hospital ED, or Christchurch Hospital ED
- Aged 2 to 23 months old (chronological age)
- Temperature of equal to or greater than 38.0 degrees Celsius (rectal/axillary/tympanic)
- Moderate or severe discomfort/pain, defined as an EVENDOL score equal to or greater than 4.

Exclusion (15)

- Infants will not be enrolled if ANY of the following apply:
- Administration of paracetamol less than 4 h or ibuprofen less than 6 h prior to trial screening (usual dosing interval)
- Already received maximum 24 h dose of paracetamol (75 mg/kg per day) or ibuprofen (age <3 months: 20 mg/kg per day; age 3-23 months: 40 mg/kg per day) in the preceding 24 h
- Known paracetamol or ibuprofen hypersensitivity
- Requiring immediate treatment for possible sepsis
- ... and 10 more (see full listing online)

Locations (1 total)

New Zealand

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624001055594>

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