Double NAC trial: Investigation of increased N-acetylcysteine dosing in patients treated for paracetamol overdose.

ACTRN12619001548123

Status	RECRUITING
Phase	Phase 3
Sponsor	Monash Health
Enrollment	230 participants

Plain Language Summary

Paracetamol (acetaminophen) is one of the most common medications taken in overdose worldwide. When taken in large amounts, paracetamol breaks down into substances that can damage the liver — sometimes severely. The standard treatment is an intravenous infusion of a medication called N-acetylcysteine (NAC), which protects the liver and helps the body clear the harmful by-products. The current standard course of NAC lasts about 20–21 hours.

However, some patients present to hospital very late after their overdose, or already have signs of liver damage. These 'high-risk' patients may not benefit enough from the standard NAC dose. This study is testing whether giving a higher dose of NAC to these higher-risk patients reduces liver injury and shortens the time they need to stay in hospital.

You may be eligible for this study if you have been admitted to hospital following a paracetamol overdose and have either abnormal liver function tests on arrival, or a very high paracetamol level in your blood. Pregnant patients and those with pre-existing liver disease are excluded, as are lower-risk patients who have normal liver tests after overdose.

Key Eligibility Criteria

Inclusion (1)

- Patients requiring NAC following single acute or staggered overdose with abnormal liver function tests on presentation (ALT>40 U/L), or paracetamol concentration more than double the nomogram treatment line, modified-release paracetamol paracetamol ingestions.

Locations (6 total)

Dandenong Hospital - Dandenong, NSW,VIC, Australia
Austin Health - Austin Hospital - Heidelberg, NSW,VIC, Australia
Casey Hospital - Berwick, NSW,VIC, Australia
... and 3 more locations