A comparison of two different durations of the antidote acetylcysteine for paracetamol overdose.

ACTRN12616001617459

Status	RECRUITING
Phase	Phase 4
Sponsor	Colin Page
Enrollment	220 participants

Plain Language Summary

This study is comparing a 12-hour versus a 20-hour course of acetylcysteine — the standard antidote for paracetamol (acetaminophen) overdose — to see if the shorter treatment works just as well in protecting the liver. Paracetamol overdose is very common and is the leading cause of liver failure in developed countries. The standard 20-hour regimen was developed in the 1970s without rigorous clinical testing. This trial asks whether a shorter course is equally effective for patients treated early.

You may be eligible if:
- You are 16 years of age or older
- You have taken a paracetamol overdose of 30g or less in a single episode
- Treatment can be started within 8 hours of ingestion
- Your blood paracetamol level is above — but less than twice — the nomogram treatment line

You may NOT be eligible if:
- You took paracetamol in multiple doses or at different times (staggered)
- You took extended-release paracetamol
- It has been more than 8 hours since you took the overdose
- Your overdose was more than 30g or your blood levels are more than twice the treatment threshold

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

Key Eligibility Criteria

Inclusion (4)

- Single immediate release paracetamol overdoses of 30g or less with an initial paracetamol concentration above but less than twice the nomogram line (paracetamol ratio <2)
- Acetylcysteine can be safely commenced within 8 hours of ingestion.
- Informed consent can be obtained.
- The paracetamol ratio is the first paracetamol concentration taken between four and 16 hours post ingestion divided by the paracetamol concentration on the 150mg/L at four-hour standard nomogram line at the same time point.

Exclusion (5)

- Staggered or repeated immediate release paracetamol overdoses.
- Single, staggered or repeated overdoses of sustained release paracetamol.
- Repeated supratherapeutic ingestion of paracetamol.
- Late presentation i.e. >8 hours since ingestion timea.
- >30g paracetamolb or paracetamol ratio >2.

Locations (3 total)

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12616001617459

Princess Alexandra Hospital - Woolloongabba, NSW,QLD, Australia
Calvary Mater Newcastle - Waratah, NSW,QLD, Australia
Prince of Wales Hospital - Randwick, NSW,QLD, Australia