INFERR - Iron Infusion in Haemodialysis Study: Effect of Intravenous Iron Polymaltose on survival and hospitalisation rates for Indigenous Patients with High Ferritin Levels on Haemodialysis

ACTRN12620000705987

Status	RECRUITING
Phase	Phase 4
Sponsor	Menzies School of Health Research
Enrollment	576 participants

Plain Language Summary

Many Aboriginal and Torres Strait Islander people in the Northern Territory require ongoing kidney dialysis (haemodialysis) due to advanced kidney disease. Anaemia — low red blood cell levels — is common in dialysis patients and is usually treated with iron. However, some patients on dialysis develop unusual blood results: they have high ferritin (a marker often used to estimate iron stores) yet their bodies still struggle to use available iron for making red blood cells.

The INFERR study is testing whether giving intravenous iron to these specific patients — those with high ferritin, low transferrin saturation, and anaemia — can safely reduce the risk of hospitalisation and death. This is an important question because current clinical guidelines are inconsistent about whether to give or withhold iron in this situation.

You may be eligible if you are 18 or older, identify as Aboriginal and/or Torres Strait Islander, have been on maintenance haemodialysis for at least three months in the Northern Territory, have anaemia with high ferritin (700–2000 mcg/L) and low transferrin saturation, and plan to remain in the NT for the next 12 months. People with known allergies to iron products or active infections at the time of enrolment are not eligible.

Key Eligibility Criteria

Inclusion (10)

- Male or female aged less than or equal to 18 years
- Identify as Aboriginal and/or Torres Strait Islander
- On maintenance haemodialysis for greater than or equal to 3 months
- Clinical laboratory results:
- a. haemoglobin less than or equal 115 gram per liter,

... and 5 more (see full listing online)

Exclusion (15)

- History of known allergic or adverse or hypersensitivity reactions to iron polymaltose or parenteral iron products;
- Already receiving iron unless they have stopped the iron therapy for greater than or equal to 4 weeks at the time of recruitment;
- Has received blood transfusion within the last 4 weeks;
- Known iron overload, haemochromatosis, haemoglobinopathy, haemolytic anaemia, aplastic anaemia, lymphoproliferative disease or cancer or on current cancer treatment
- Participant's primary clinician unwilling to enrol

... and 10 more (see full listing online)

Locations (2 total)

Royal Darwin Hospital - Tiwi, NT, Australia

Alice Springs Hospital - Alice Springs, NT, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620000705987